

**EPA REGISTRATION NUMBER 71693-1 – VOLUME 6**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

MAR 09 2011

Dr. Michael Braverman  
Agent for Arizona Cotton Research and Protection Council  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201 W  
Princeton, NJ 08540

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Re: Arizona Cotton Research and Protection Council; *Aspergillus flavus* AF36  
EPA Registration No. 71693-1  
Amendment to add corn uses to the label  
Submissions dated 11/30/2009 and 12/15/2010  
Decision No. 424829

Dear Dr. Braverman:

The amendment referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that, within 15 days of the date of this letter, you submit a revised label to EPA, incorporating the changes listed below:

1. For the corn sublabel, add a restriction that the product is "FOR USE ONLY IN THE STATES OF TEXAS AND ARIZONA."
2. For the corn sublabel, add the EPA Registration Number, 71693-1.

If you have any questions regarding this letter, please contact Ms. Jeannine Kausch by telephone (703-347-8920) or email ([kausch.jeannine@epa.gov](mailto:kausch.jeannine@epa.gov)).

A stamped copy of the label is enclosed for your records.

Sincerely,

Keith A. Matthews, Director  
Biopesticides and Pollution  
Prevention Division (7511P)

Enclosures (1):  
-*Aspergillus flavus* AF36 Accepted Label

Dr. Michael Braverman  
 Agent for Arizona Cotton Research and Protection Council  
 IR-4 Project, Rutgers University  
 500 College Road East, Suite 201W  
 Princeton, NJ 08540

MAR 09 2011

Re: Arizona Cotton Research and Protection Council; *Aspergillus flavus* AF36  
 EPA Registration No. 71693-1  
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 Decision No. 424829

Dear Dr. Braverman:

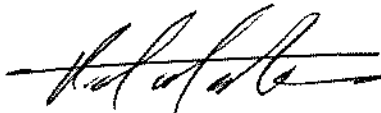
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Sincerely,



Keith A. Matthews, Director  
 Biopesticides and Pollution  
 Prevention Division (7511P)

Enclosures (1):  
 -*Aspergillus flavus* AF36 Accepted Label

## CONCURRENCES

SYMBOL	7511P	7511P	7511P					
SURNAME	KAUSCH	Reynolds	Matthews					
DATE	03/09/2011	3/9/11	09 Mar 11					

# *Aspergillus flavus* AF36

## MASTER LABEL

**Sublabel A: Cotton**

**Sublabel B: Corn**

**Active Ingredient:**

<i>Aspergillus flavus</i> strain AF36*	0.0008%
Other Ingredients	99.9992%
Total	100.0000%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

EPA Registration No. 71693-1

EPA Est. No. 71693-AZ-001

Arizona Cotton Research and Protection Council

Phoenix, AZ 85040

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
MAR 09 2011**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
71693-1



# Aspergillus flavus AF36

FOR USE ONLY IN THE STATES OF ARIZONA, TEXAS  
AND CALIFORNIA (Imperial, Riverside and San Bernadino counties only)

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied to cotton just prior to first bloom, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: *Aspergillus flavus* strain AF36\* ..... 0.0008%  
Other ingredients: Wheat seeds (sterilized, colonized)..... 99.9992%  
100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693-1  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

## PRECAUTIONARY STATEMENTS

### HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

For other pesticide handlers under the scope of Worker Protection Standard:

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

#### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

## ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other

waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated cotton fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses; and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

##### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls; long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

#### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to cotton to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed, which serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur at irrigation), *Aspergillus flavus* AF36 will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi are spread.

##### Ground Application:

1. Apply *Aspergillus flavus* AF36 with a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 under the canopy and to minimize delivery of *Aspergillus flavus* AF36 to furrows.
3. *Aspergillus flavus* AF36 has been shown to be effective when applied in late May or early June, prior to first bloom. Make a single application during the last cultivation before bloom.
4. Furrow irrigating the crop with at least 2 inches of water within three days after application of *Aspergillus flavus* AF36 will provide the best results.
5. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application may diminish efficacy.

#### STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**Returnable/Refillable Bulk Containers-** Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

# Aspergillus flavus AF36

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized)	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

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EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
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NET CONTENTS: 50 lbs, 1000-3000 lbs

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### DIRECTIONS FOR USE

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*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

##### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

#### STORAGE AND DISPOSAL

**DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.**

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#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.



**NATIONAL  
CORN GROWERS  
ASSOCIATION**

February 22, 2011

Dr. Steven Bradbury  
Director, Office of Pesticide Programs  
U.S. Environmental Protection Agency  
2777 S. Crystal Drive  
Arlington, VA 22202-3553

Dr. Bradbury:

For a number of years, the National Corn Growers Association has taken a leading role in the effort to mitigate the presence and impact of aflatoxin in corn. It remains a critical issue for many of our growers, particularly in the south, who often face aflatoxin pressure.

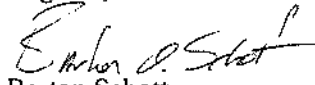
Since 2006, the Texas Corn Producers Board has funded research conducted by Dr. Peter Cotty at the University of Arizona to evaluate the efficacy of a particular biopesticide, AF 36, on corn in Texas. This was done under an Experimental Use Permit (EUP) issued by your Agency. Under the EUP, we have had three years of direct applications of AF 36 to corn acres in Texas, and the product shows real promise. In certain field trials, AF 36 reduced the presence of aflatoxin to less than 20 parts per billion while other nearby untreated fields were often in excess of 300 parts per billion.

While the EUP expired on December 31, 2010, we know that the Agency received a Section 3 application for AF 36 on December 20 and that the product was assigned to a reviewer in the Biopesticides and Pollution Prevention Division. Under the Pesticide Registration Improvement Act, we understand the negotiated deadline for a registration decision currently stands at August 17, 2011.

We are requesting that EPA expedite the review of this important product. If a Section 3 registration is not approved in time to allow for distribution in preparation for the Texas growing season, we face losing important continuity that we have been able to achieve on corn acres in Texas over the past few years. If possible, we urge EPA to issue a registration prior to April 1.

NCGA has rarely, if ever, requested an expedited review of a product registration; however, this is a unique circumstance due to the lack of tools available to combat the aflatoxin problem. Please let us know if we can be of assistance or if any additional information from the grower community might be helpful.

Regards,

  
Barton Schott  
President

**WWW.NCGA.COM**

**NATIONAL OFFICE**  
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Chesterfield, MO 63005  
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Washington, DC 20001-2109  
(202) 628-7001  
Fax: (202) 628-1933

→ Sheryl Reilly  
NOR -

March 12, 2010

To: Keith A. Matthews

Acting Director, Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs, Environmental Protection Agency

Re: Docket Number: EPA-HQ-OPP-2010-0089

Environmental Protection Agency [EPA-HQ-OPP-2010-0110; FRL-8811-1]

Federal Register Notice, Volume 75, Number 27, pages 6656-6657, February 10, 2010

Pesticide Product; Registration Application

Registration Number: 71693-1

Company Name and Address: Arizona Cotton Research and Protection Council

3712 East Wier Avenue

Phoenix, AZ 85040-2933

Active Ingredient: *Aspergillus flavus* AF36

Proposed Use: On corn

Cc: Sheryl Reilly, Branch Chief, Biopesticides and Pollution Prevention Division, OPP, EPA  
Shanaz Bacchus, Biopesticides and Pollution Prevention Division, OPP, EPA

Dear Mr. Matthews,

I am very recently retired from USDA ARS, where I worked as a researcher for 35 years, specializing in mycotoxin contamination and the development of biopesticides for the reduction of aflatoxin contamination in agricultural crops. I have led or participated in numerous studies regarding the mycotoxins produced by fungi in the genus *Aspergillus*, and I hold several U. S. patents and have authored or co-authored over 150 publications in this field. I am writing to register my very serious concerns, based on significant research and experience, regarding the action proposed in the subject FR Notice and to request the EPA to deny the application for registration of *Aspergillus flavus* AF36 on corn.

Moving forward with the proposed action will expose U. S. corn growers, aggregators, exporters, processors, livestock and poultry producers, pet food manufacturers, and the general public to unmanaged risk of exposure to artificially elevated levels of a currently unregulated mycotoxin, cycloplazonic acid (CPA). CPA may be produced in significant concentrations by the AF36 strain of *Aspergillus flavus* (also designated as NRRL 18543), as an unintended consequence of the use of AF36 as a biopesticide to reduce the levels of aflatoxins. In the best case, corn-based food and feed chains may be forced to bear additional, unnecessary costs to monitor and manage the presence of this toxin in corn intended for food, feed, or export. In the worst case, significant episodes of human and/or animal toxicity could occur if monitoring and mitigation are not routinely and effectively practiced. Even if these human and animal health risks do not immediately result in significant events of toxicity within the US or abroad, there is also the threat of international trade disruption as awareness of the

implications of the field use of this product become more widely known. The EU and Japan are generally more conservative in their approach to mycotoxins in food and feed than the US, often setting lower limits for their presence in agricultural commodities and enforcing their standards with great energy. Finally, the entire approach of using biopesticides that work by competitive exclusion to reduce aflatoxin contamination of agricultural crops could easily be discredited, robbing growers of existing and future alternative biopesticide products which do not present this unacceptable risk. While the risks associated with limited use of AF36 on cotton in Arizona and Texas may have been acceptable, registration of this product for use in corn would pose unreasonable risks and, therefore, this application for registration should be denied.

#### Mycotoxins produced by *A. flavus* strains

Species within the genus *Aspergillus* are among the most common toxigenic fungi affecting food and feed crops. They are capable of producing several different toxins, with the aflatoxins being of greatest concern. *A. flavus*, the *Aspergillus* species most commonly involved in contamination of agricultural commodities, may produce aflatoxins B1 and B2, while the closely related *A. parasiticus* may produce aflatoxins B1, B2, G1, and G2. These toxins are the subject of monitoring and regulation in affected agricultural commodities worldwide (1).

Certain, but not all, strains of *A. flavus* are also capable of producing CPA, an indole, tetramic acid mycotoxin that was first isolated from cultures of *Penicillium cyclopium* in 1968 (2). CPA is now known to be produced by several fungal species in the genera *Penicillium* and *Aspergillus* and has been found as a natural contaminant of corn and peanuts, often as a co-contaminant with aflatoxin (3-7). Gallagher et al. (3) examined 54 isolates of *A. flavus* for production of CPA and aflatoxin, and found that 28 of the 54 (52%) produced CPA whereas only 18 (33%) produced aflatoxin. Similarly, Horn and Dörner (8) found that production of aflatoxins and CPA were not necessarily linked in strains of *A. flavus* collected across the southern US. AF36 is one such CPA-producing, non-aflatoxigenic strain, and this has been documented in the literature (9, 10).

#### Toxicity of CPA

CPA is toxic to animals and humans, with varying degrees of sensitivity observed in different animal species. Two recent review articles by Burdock and Flamm (11) and Chang et al. (1) provide a good overview of the current state of knowledge regarding CPA and many valuable references, but Chang et al. note that CPA has received much less attention from the research community over the past 20 years than aflatoxins, fumonisins and other higher priority toxins; so the actual body of knowledge is relatively limited when compared to that which exists for these high priority toxins.

CPA's mode of toxicity, however, has been well studied. CPA's toxicity is based on the alteration of normal intracellular calcium flux through the specific inhibition of sarcoplasmic or endoplasmic reticulum calcium-dependent ATPase (SERCA). This alteration of calcium uptake affects the muscle contraction-relaxation cycle, resulting in increased muscle contraction. SERCA also plays a crucial "housekeeping" role in other body cells, managing the calcium gradient between the endoplasmic

reticulum and the cytoplasm, which is vital in controlling cell proliferation, differentiation and cell death (12-14).

Besides the specific inhibition of ATPase activity, CPA has been shown to induce various pathological lesions in test animals including:

- Rats: lesions of the liver, kidney, pancreas, spleen, and heart (post intraperitoneal injection) (15-17);
- Nonpregnant mice: oral LD50 value 64 mg/kg body weight, with dose dependent toxicity syndromes including ptosis, hypokinesia, hypothermia, tremor, cessation of food and water intake and resulting cachexia (18);
- Pregnant mice: a single oral pulse dose of 15 to 50 mg/kg significantly decreased body weight gain and pregnancy rates (18);
- Broiler chickens: high mortality rate and decreased weight gain when fed CPA at 100 ppm. Postmortem examination showed proventricular lesions characterized by mucosal erosion and hyperemia, yellow foci in livers and spleens. Microscopic examination of tissues showed ulcerative proventriculitis, mucosal necrosis in the gizzard, and hepatic and splenic necrosis and inflammation. Chickens fed 50 ppm CPA had thick mucosa and dilated proventricular lumens as well as hyperplasia of the proventricular mucosal epithelium. CPA at 10 ppm, however, did not cause significant lesions (19, 20, 30);
- Dogs: Dogs are particularly susceptible to the effects of CPA. Dogs dosed with CPA at 0.5 mg/kg or 1.0 mg/kg died before the end of a 90-day study period, which suggests a much lower no-observable-effect level (NOEL) than other small animals. When administered to dogs, the clinical signs of CPA-intoxication appeared within two days and consisted of anorexia, vomiting, diarrhea, pyrexia, dehydration, weight loss, and central nervous system depression. The entire alimentary tract had diffuse hyperemia with focal areas of hemorrhage and ulceration (21);
- Pigs also appear to be very sensitive to CPA with a NOEL of approximately 1.0 mg/kg (22).

Though few incidents of CPA-related animal mycotoxicosis have been documented, Chang et al. (1) suggest that this may be because CPA is not acutely toxic at low doses, the amounts present in food and feed may usually be low, and/or because its effects may be masked by or attributed to other co-contaminating mycotoxins. It is important to note that both CPA and aflatoxins were isolated from the peanut meal implicated in the turkey 'X' disease which caused the death of 100,000 turkeys in England in the early 1960s and spurred the effort to identify and characterize the causative toxin(s) (23-26). Although aflatoxins are still regarded as the main culprit in this incident, CPA's contributory role is supported by the fact that some of the observed symptoms and pathological clinical signs in affected animals, such as catarrhal or haemorrhagic enteritis and opisthotonus, are not characteristic of aflatoxicosis but can be caused by CPA (23, 25, 27).

Similarly, field incidents of CPA mycotoxicoses in humans have not been fully proven, though there is significant evidence that CPA was implicated in episodes of 'kodo poisoning' reported in Northern India in the 1980's, a toxic reaction observed in people who had consumed CPA-contaminated kodo millet. Kodo poisoning is characterized by nausea, vomiting, depression, intoxication and unconsciousness. (28, 29).

A very limited number of studies examining the combined toxicological effects of CPA and aflatoxin, ochratoxin or T-2 toxin have been conducted, but these have all been short-term studies, largely



showing additive effects (30-35). Again, longer term studies involving co-contamination have not been conducted.

The acute oral LD50 in rats for CPA has been estimated to be in the range of 30 to 70 mg/kg (1), while the corresponding LD50 value for aflatoxin B1 is estimated at 5.5 to 17.9 mg/kg (36). Burdock and Flamm (11) have suggested that, based on a NOEL of 1 mg/kg/day and taking into consideration species variability, for humans approximately 10 µg/kg/day or 700 µg/day would represent the maximum acceptable daily intake (ADI) dose.

#### Genetics of "Non-Aflatoxigenic" *Aspergillus* Strains

AF36 is one of many strains of *Aspergillus flavus* which have been isolated and characterized by researchers as "non-aflatoxigenic". *A. flavus* strain NRRL 21882, the active ingredient in the commercially available product Afla-Guard®, has also been determined to be non-aflatoxigenic (10).

The inability to produce aflatoxins has been shown to be the result of defects in the gene cluster responsible for the production of these potent and carcinogenic toxins (10, 37). Even before the genome sequences of *A. oryzae* and *A. flavus* became available it was suspected that the genes involved in CPA production are located close to the aflatoxin gene cluster because many *A. flavus* strains unable to produce aflatoxins also do not produce CPA. Chang et al. found that isolates that produce neither aflatoxins nor CPA had lost large portions of or the entire aflatoxin gene cluster up to the telomere (10) and that the genes coding for production of CPA are in this same region (34).

Chang et al. (10) reported that NRRL 21882 was a strain with a deletion of the entire aflatoxin gene cluster from the hexA coding region in the sugar utilization gene cluster to the telomeric region, and an associated inability to produce either aflatoxins or CPA.

Similar genetic characterization of AF36 (38) shows that the interruption of aflatoxin production in this strain is based on a single nucleotide polymorphism near the beginning of the coding sequence of the polyketide synthase gene (pksA). This nucleotide change introduces a premature stop codon into the coding sequence for this enzyme, thereby preventing enzyme production and aflatoxin accumulation in AF36, and in other members of the same vegetative compatibility group. This highly specific genetic defect has no diminishing effect on the production of CPA.

#### Field Use of AF36 May Lead to High Levels of CPA

In a field study reported by Dorner et al. (9), peanuts harvested from plots treated with AF36 had a much higher level of CPA than either the untreated control or plots treated with NRRL 21882, the active ingredient in the commercial product Afla-Guard® (see below a reproduction of Table 4 from reference 9). Given that this trial was conducted under conditions that resulted in only modest levels of aflatoxin in the untreated plots, this dramatic increase in CPA levels over the background level in the controls suggests that under more severe conditions, CPA levels could be extremely high, and much, much higher than would be present in the absence of treatment with AF36.

TABLE 4

<u>Aflatoxin and Cyclopiazonic Acid in Peanuts.</u>					
		<u>Edible Peanuts</u>		<u>All Peanuts</u>	
Treatment		Aflatoxin	CPA	Aflatoxin	CPA
Control	1	8.4	0.0	195.3	18.2
	2	44.0	3.7	44.8	3.1
	3	5.0	3.1	18.9	6.4
	4	27.7	0.0	156.4	8.9
	Mean	21.5	1.7	103.9	8.7
NPL45 (NRRL 21882)	1	1.4	0.0	155.4	9.7
	2	7.5	0.0	124.1	7.0
	3	0.0	0.0	2.2	0.0
	4	8.6	0.0	20.8	4.3
	Mean	4.4	0.0	75.6	5.3
AF 36	1	0.5	191.4	35.3	760.2
	2	11.5	18.5	160.3	100.2
	3	21.1	0.0	90.5	82.6
	4	0.1	69.2	20.2	344.3
	Mean	8.3	69.8	76.6	321.9

After Dorner et al. (9)

#### Registration of AF36 on Corn Would Pose an Unacceptable Risk

Approximately 8 million acres are planted to corn in the southern U. S., the geography most routinely at-risk for aflatoxins. A total of over 80 million acres of corn are planted and harvested in the US each year. Corn is widely used in human food and animal feed, and is an important export commodity.

In spite of the overwhelming evidence of the significance of CPA, it has not been regulated by the U. S. Food and Drug Administration (FDA). Reasons for this probably include the facts that it is difficult and expensive to analyze for and that it often co-occurs in agricultural commodities with aflatoxin. Aflatoxin is regulated at very low levels by the FDA and its presence in a host of commodities is heavily monitored. Therefore, steps taken to divert aflatoxin-contaminated food and feed away from the food and feed chains usually result in the diversion of CPA-contaminated food and feed as well. It is very likely that this is the primary reason that CPA has not been implicated in more mycotoxicoses in the U. S. and other developed countries that do extensive aflatoxin monitoring.

Therefore, it is extremely important to ensure that any biopesticide using a non-aflatoxigenic strain of *Aspergillus flavus* as its active ingredient does not produce other harmful metabolites, such as CPA. AF36 is demonstrated to have the capacity to contaminate crops with levels of CPA far above naturally

occurring levels. It is important for the protection of human and animal health that the EPA does not move forward to approve the registration of AF36 for use on corn.

I would welcome the opportunity to discuss this with you or to provide additional information as needed. Please contact me at (229) 436-5515 or by email at [jwdorner@bellsouth.net](mailto:jwdorner@bellsouth.net).

Regards,



Joe W. Dorner, MS  
Research Microbiologist  
USDA, ARS (Retired)

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→ Sheryl Reilly

March 12, 2010

To: Keith A. Matthews

Acting Director, Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs, Environmental Protection Agency

Re: Docket Number: EPA-HQ-OPP-2010-0089

Environmental Protection Agency [EPA-HQ-OPP-2010-0110; FRL-8811-1]  
Federal Register Notice, Volume 75, Number 27, pages 6656-6657, February 10,  
2010

Pesticide Product; Registration Application

Registration Number: 71693-1

Company Name and Address: Arizona Cotton Research and Protection Council  
3712 East Wier Avenue  
Phoenix, AZ 85040-2933

Active ingredient: *Aspergillus flavus* AF36

Proposed Use: On corn

Cc: Sheryl Reilly, Branch Chief, Biopesticides and Pollution Prevention Division, OPP,  
EPA

Shanaz Bacchus, Biopesticides and Pollution Prevention Division, OPP, EPA

Dear Mr. Matthews,

I appreciate the opportunity to comment on Registration Number 71693-1, Docket Number: EPA-HQ-OPP-2010-0089. This is in regard to the submission by Arizona Cotton Research and Protection Council regarding the active ingredient, AF36 for use-expansion to corn.

I am a plant pathologist (Ph.D. UC Davis, 1982). I have worked for Colorado State University, DuPont, Mycogen (the biological control company), and for the past 14 years as an independent consultant ([www.cirruspartners.com](http://www.cirruspartners.com)).

I first learned about the "atoxigenic strain" approach to aflatoxin reduction in 1992 when I invited Dr. Peter Cotty of the USDA to come and describe his work at Mycogen. I was initially skeptical that it would be possible to sufficiently shift population genetics in a field situation, but Peter had compelling data. I tried, but I was unfortunately unable to persuade my company to license this technology at that time. Still, I followed it closely after that visit.

Overall I think that mycotoxin reduction is an extremely important goal for our food system and I believe that biological control can play a key role in that effort along with other approaches. I have been trying to educate the broader public about the

importance of mycotoxins – not in an alarmist manner - but as a way to put various risks into perspective. Since July of last year I have put up several mycotoxin-related blog postings. These have been widely viewed and generated interesting comment streams and emails.

<http://blog.sustainablog.org/an-agricultural-scientists-food-supply-worries-part-2-vomitoxin/>

<http://blog.sustainablog.org/food-supply-worries-of-an-agricultural-scientist-part-4-aflatoxin/>

<http://blog.sustainablog.org/why-wheat-is-an-orphan-crop-conclusion/>

<http://www.simplygreen.co.za/articles/articles/if-theres-a-toxin-in-the-food-supply-but-no-corporation-to-blame-is-it-still-a-problem.html>

I certainly care about this issue and am supportive of a biocontrol solution, but I have some specific concerns about the Section III for AF36 on corn.

The AF36 atoxigenic strain of *Aspergillus flavus* came from the important, pioneering work of Dr. Peter Cotty,

<http://azcotton.org/AF36/AF36%20COVER%20PAGE.htm>

but even though this strain makes no aflatoxin, it does make another intermediary metabolite that is a mycotoxin called cycloplazonic acid (CPA)

<http://www.mdpi.com/2072-6651/1/2/74>

<http://dx.doi.org/10.1016/j.toxlet.2009.06.482>

Even though CPA is not nearly as toxic as aflatoxin, it is still an undesirable chemical to have in the food chain where not necessary.

CPA's toxicity has been quite well documented as has its tendency to transfer to the meat and milk of animals that consume it.

<http://pubs.acs.org/doi/abs/10.1021/1f00079a028>

<http://www.informaworld.com/smpp/176802440-7875308/content~db=all~content=a906938604>

CPA is not currently a regulated toxin by FDA, but perhaps it should be. If a chemical of that toxicity were found to be unintentionally present in a synthetic pesticide product, it would certainly not be registered.

The production of unacceptably toxic substances by biocontrol organisms is not without precedent. Long-used strains of *Bacillus thuringiensis* that produce the extremely benign protein endotoxins can also produce "exotoxin" which is sufficiently dangerous that all fermentation batches of B.t. have to be checked to make sure they do not have this natural, but nasty component. In the case of AF36, whether CPA is produced cannot be determined by batch because the fungus would produce this in the field - at the same time it is suppressing aflatoxin-producing strains through competitive exclusion. In fact, the levels of CPA in a crop will tend to be enhanced over natural background when this biocontrol strain is used.

If AF36 were the only biocontrol option available to minimize aflatoxin in the crops covered by this Section III, I might not have any objection. However, Dr. Cotty's work was followed-up by another USDA researcher, Dr. Joe Dorner, who has developed an alternate, atoxigenic strain (NRRL 21882) which has the same biocontrol efficacy but which does not make CPA.

<http://www.sumobrain.com/patents/wipo/Biological-control-aflatoxin-cyclopiazonic-acid/WO20000001232.html>

In fact, the full genetic explanation for the absence of the entire "aflatoxin gene cluster" has been documented.

<http://ddr.nal.usda.gov/dspace/bitstream/10113/36186/1/IND43774217.pdf>

A small company called Circle One Global, Inc. commercialized that strain as "Afla-Guard". That product was recently sold to Syngenta who will hopefully be able to expand the use of this unconventional product.

The EPA is well aware of the absence of CPA in the Afla-Guard product and required that the absence of that toxin and kojic acid be demonstrated for a Section III registration.

[http://www.epa.gov/pesticides/biopesticides/ingredients/tech\\_docs/brad\\_006500.pdf](http://www.epa.gov/pesticides/biopesticides/ingredients/tech_docs/brad_006500.pdf)

The Federal Register entry for a tolerance for Afla-Guard talks about the absence of CPA as a positive attribute

<http://edocket.access.gpo.gov/2004/04-6002.htm>

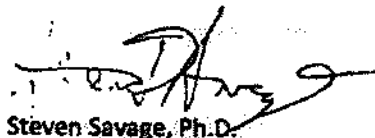
After more than 32 years of working in agriculture, my primary loyalty is to growers. This is true even though I have mostly worked for companies that provide tools to growers. My hat is off to the Arizona Cotton Research and Protection Council for having had the vision to help commercialize this biocontrol agent (as I said, I was unable to get my company to do this in the early 1990s). The only reason I go against my grower bias



and oppose this Section III is that I see it as a risk to the underlying biocontrol approach for mycotoxins.

The broader public has virtually no understanding that mycotoxins exist or how dangerous they are. Our food system actually does a respectable job of managing that risk, but it could do better with technologies like "atoxigenic strains." I would personally like to see a similar, biological approach extended to the many other mycotoxin issues in our food supply (vomitoxin, fumonisin, ochratoxin...). AF36 is currently a tiny, niche product, but there is the potential for significant public reaction if it became known that a fungal strain producing a documented toxin was being intentionally introduced into the feed/food chain. It may be unlikely that it would ever become a public issue. Consider how the popular press completely failed to pick up on the unprecedented level of vomitoxin (DON) contamination in the 2009 corn crop that was an almost daily news event in the farm press this fall and winter. Still, considering the broader potential of the "competitive exclusion approach" to manage a materially significant health threat in the food supply, it does not seem logical to approve the use of a strain with known toxin production potential when there is a comparable strain without such potential. How would the EPA, USDA, FDA, or even the Arizona Cotton Research and Protection Council explain that to the broader public in the event that this was necessary?

Sincerely,



Steven Savage, Ph.D.

Cirrus Partners, LLC ([www.cirruspartners.com](http://www.cirruspartners.com))

Encinitas, CA 92024

760-634-5553

## Memorandum

Date: 1/31/11

To: PM 92, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission

# DATA PACKAGE BEAN SHEET

Date: 07-Feb-2011

Page 1 of 2

Decision #: 444580

DP #: (386585)

PRIA

Parent DP #:

Submission #: 889198

## \*\*\* Registration Information \*\*\*

Registration: 71693-1 - Aspergillus Flavus AF36

Company: 71693 - ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

Risk Manager: RM 92 - Sheryl Reilly - (703) 308-8269 Room# PY1 S-8741

Risk Manager Reviewer: Shanaz Bacchus SBACCHUS

Sent Date: \_\_\_\_\_

Calculated Due Date: 06-Oct-2011

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (B631) AMEND ESTABLISHED TOLERANCE EXEMPTION;

Ingredients: 006456, Aspergillus flavus 36 colonized wheat seed(.0008%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 07-Feb-2011

Due Back: \_\_\_\_\_

DP Ingredient: 006456, Aspergillus flavus 36 colonized wheat seed

DP Title: efficacy data - pistachio

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: \_\_\_\_\_

### Assigned To

Date In

Date Out

Organization: BPPD / MPB

07-Feb-2011

Last Possible Science Due Date: 09-Jan-2011

Team Name: MPB Eco Science Review

07-Feb-2011

Science Due Date: \_\_\_\_\_

Reviewer Name: Gagliardi, Joel

07-Feb-2011

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Please review attached MRID 48363701 for efficacy of Aspergillus flavus AF36 on pistachio. Do the data support an exemption from tolerance and an amendment for the registration to add pistachio to the label under FIFRA section 3?

DP#: (386585)

\*\*\* Studies Sent for Review \*\*\*

Decision#: (444580)

MRID	MRID Status	Citation Reference	Guideline
48363701		Michilides, T.; Doster, M.; Cotty, P.; et al. (2010) Efficacy Data for <i>Aspergillus flavus</i> - AG36 in or on Pistachio. Project Number: 0327B. Unpublished study prepared by Interregional Research Project No. 4, USDA-ARS and University of California Kearney Agricultural Center. 99 p.	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

January 31, 2011

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

CHARLENE R. NEAL  
ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL  
3721 EAST WIER AVENUE  
PHOENIX, AZ 85040-2933

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 16-DEC-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# Receipt for Section 3

S: 888198

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 71883 ARIZONA COTTON RESEARCH AND PROTECTIO

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92

Product #: 71893-1 Product Name: Aspergillus Flavus AF36

Override:

Me Too Section 3: Me Too Product Name:

Application Date: 06-Dec-2010

OPP Rec'd Date: 16-Dec-2010

Front End Date: 25-Jan-2011

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

to add pistachio to the label

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study	
CSF	

View/Edit

New Ingredient Request Date:

New Ingredient Received Date:

# Aspergillus flavus AF36

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, cottonized).....	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

### PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

**For other pesticide handlers under the scope of Worker Protection Standard:**

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

#### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated corn fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

##### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

#### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

##### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

#### STORAGE AND DISPOSAL

**DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.**

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**Returnable/Refillable Bulk Containers-** Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.



# Aspergillus flavus AF36

Proposed label

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized)	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
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Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

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EPA Registration Number 71693  
EPA Establishment Number: 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

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**For other pesticide handlers under the scope of Worker Protection Standard:**

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

## ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

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#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

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2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
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4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

#### STORAGE AND DISPOSAL

##### DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

December 27, 2010

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

CHARLENE R. NEAL  
ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL  
3721 EAST WIER AVENUE  
PHOENIX, AZ 85040-2933

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 20-DEC-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# Receipt for Section 3

S: 887567

Reasons: ☒ Yes ☐ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☐ Yes ☒ No

Company: 71693 ARIZONA COTTON RESEARCH AND PROTECTIO V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92

Product #: 71693-1 Product Name: Aspergillus Flavus AF36

Overrides:

Me Too Section3: Me Too Product Name:

Application Date: 15-Dec-2010

OPP Rec'd Date: 20-Dec-2010

Front End Date: 20-Dec-2010

Risk Manager Send Date: 20-Dec-2010

FFS Due Date: 13-Nov-2010

Negotiated Due Date: 17-Aug-2011

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

response to 75-day letter

Form A: ☐ Signature Date:

Form B: ☐

New Ingredient Request Date:  
New Ingredient Received Date:  
Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

View/Edit

# Receipt for Tolerance Petition

S: 887568

Resubmission: ☒ Yes ☐ No

Regulatory Type: Tolerance Petition

Fee For Service: ☐ Yes ☒ No

Application Type: New Registration

Billable: ☐ Yes ☒ No

Company: 71693 ARIZONA COTTON RESEARCH AND PROTECTIO V

Risk Mgr: Biologicals & Pollution Prevention Division, PM Team 92

Petition #: 9E7662 Fee Waived: ☐ Yes ☒ No Fee:

Petition Type: E - Minor Use (IR-4/State)

Print Letter

Enter More Information

Tracking

Application Date: 15-Dec-2010

OPP Rec'd Date: 20-Dec-2010

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Risk Manager Send Date: 20-Dec-2010

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OPP Target Date:

Receipt Content	Des
Study	

View/Edit

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

response to 75-day letter

New Ingredient Request Date  
New Ingredient Received Date  
Signature Date

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:





Providing Safe and Effective Pest  
Management Solutions for  
Specialty Crop Growers

483301-00

IR-4 Headquarters  
Rutgers, The State University of New Jersey  
500 College Road East, Suite 201 W  
Princeton, NJ 08540  
732.932.9575  
fax: 609.514.2612  
ir4.rutgers.edu

Shanaz Bacchus, Regulatory Action Leader  
c/o Document Processing Desk  
Office of Pesticide Programs (7504P)  
Biopesticides & Pollution Prevention Division (BPPD)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501  
(703)308-8097

December 15, 2010

RE: Registration AF36 (*Aspergillus flavus* AF36) on Corn  
Company Number 71693-1 PP 9E7662 IR-4 PR# 0378B

Dear Shanaz

This submission is in response to a 75 day letter from Dr Sheryl Reilly dated October 6, 2010(attached)regarding the request for additional efficacy data for AF36 on corn. Data from 2008 was previously submitted (MRID 47935101)and this current submission includes 2009 data. Please find attached , Form 8570-1 Application for Pesticide for the use of an atoxigenic *Aspergillus flavus* AF36 to displace toxigenic *Aspergillus flavus* on corn. I have also attached 5 copies of the corn label for your review.

The two years of field data are consistent and the primary conclusions drawn from this research are as follows:

1. **AFLATOXIN:** In both 2008 and 2009, aflatoxin concentration in corn grain from fields treated with AF36 were less than in corn grain from fields not treated. Aflatoxin concentration decreased as incidence of AF36 increased (there was a significant inverse correlation)
2. **CYCLOPIAZONIC ACID:** In both 2008 and 2009, CPA concentration was not significantly different in corn grain from fields treated with AF36 than in corn grain from fields not treated. AF36 incidence was not significantly correlated with CPA concentration, but the overall trend was that as AF36 incidence increased, CPA concentration decreased.

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES,  
in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.

**RUTGERS**  
THE STATE UNIVERSITY  
OF NEW JERSEY



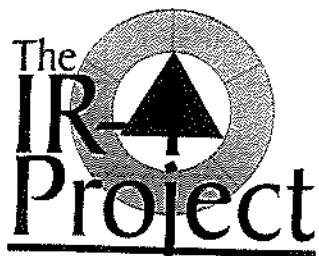
**DATA ASSOCIATED WITH THIS SUBMISSION**

**48330101** Volume 1 of 1 Product Performance Data: Efficacy of AF36 in Corn 2009  
Commercial Field Tests. **Amendment #1 to MRID 47935101** Dec 13, 2010  
58 pages.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Braverman". The signature is fluid and cursive, with the first name "Michael" and last name "Braverman" clearly distinguishable.

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612



Providing Safe and Effective Pest  
Management Solutions for  
Specialty Crop Growers

483637-00

IR-4 Headquarters  
Rutgers, The State University of New Jersey  
500 College Road East, Suite 201 W  
Princeton, NJ 08540  
732.932.9575  
fax: 609.514.2612  
ir4.rutgers.edu

Shanaz Bacchus, Regulatory Action Leader  
Biopesticides and Pollution Prevention Division  
c/o Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501  
703-308-8097

December 14, 2010

PETITION IR-4 Fee exempt

Subject: **Section 3 Petition** for Exemption from tolerance for *Aspergillus flavus* AF36 on  
Pistachio. Company number 71693 IR-4PR#0327B

Dear Shanaz

Enclosed, please find a petition for the above subject product. Attached please find the  
petition with Sections A-G. This petition is being submitted on behalf of the Arizona Cotton  
Research and Protection Council. IR-4 received a request from the state of California to  
petition EPA for this tolerance exemption.

An electronic copy of the Notice of Filing is being submitted under separate cover

As per PR Notice 88-4, the registration of the above use is exempt from fees.

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## **Memorandum**

Date: 12 / 29 / 10

To: PM: 92, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission

# Administrative Materials



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ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL  
3721 E WIER AVE  
PHOENIX AZ 85040-2933  
602-438-0059 (PH)  
602-438-0407 (FAX)

Shanaz Bacchus, Regulatory Action Leader  
c/o Document Processing Desk  
Office of Pesticide Programs (7504P)  
Biopesticides & Pollution Prevention Division (BPPD)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501  
(703)308-8097

December 15, 2010

RE: Registration AF36 (*Aspergillus flavus* AF36) on Corn  
Company Number 71693-1 PP 9E7662

Dear Shanaz

Please find attached , a Notice of Filing and Form 8570-1 Application for Pesticide for the use of an atoxigenic *Aspergillus flavus* AF36 to displace toxigenic *Aspergillus flavus* on corn. This submission is in response to the letter from EPA dated October 6, 2010. This letter also authorizes EPA to review all pertinent data for *Aspergillus flavus* AF36 previously submitted to EPA in conjunction with this registration.

Sincerely,

Larry Antilla  
Sponsor and Submitter  
Staff Director  
Arizona Cotton Research and Protection Council



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

<b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460		<input type="checkbox"/> <b>Registration</b> <input checked="" type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other</b>	OPP Identifier Number: _____
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number 71693		2. EPA Product Manager Shanaz Bacchus	
4. Company/Product (Name) Aspergillus flavus AF36		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933  <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____	
<b>Section - II</b>			
<input type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>Oct 6, 2010</u>		<input type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Other - Explain below.	
<b>Explanation:</b> Use additional page(s) if necessary. (For section I and Section II.)  This submission is in response to EPA's request for additional efficacy data on <u>Corn</u> as per the letter dated October 6, 2010.			
<b>Section - III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>Bulk boxes, bags</u>
* Certification must be submitted If "Yes" Unit Packaging wgt. <u>1.8g</u> No. per container <u>1</u>		If "Yes" Package wgt. <u>t</u> No. per container <u>1</u>	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container <u>Plastic bag, bulk box 50,1000, 3000 lb</u>	
5. Location of Label Directions <input checked="" type="checkbox"/>		6. Method in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
<b>Section - IV</b>			
1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name <u>Michael Braverman, Ph.D</u>		Title <u>Biopesticide Manager, IR-4</u>	
		Telephone No. (Include Area Code) <u>732-932-9575 ext 4610</u>	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			5. Date Application Received  <b>(Stamped)</b>
2. Signature 		3. Title <u>Staff Director</u>	
4. Typed Name <u>Larry Antilla</u>		5. Date <u>12-6-10</u>	

# *Aspergillus flavus* AF36

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized)	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

## PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

**For other pesticide handlers under the scope of Worker Protection Standard:**

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

## ENVIRONMENTAL HAZARDS



Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated corn fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

##### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

#### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

##### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. **DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.**
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

#### STORAGE AND DISPOSAL

**DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.**

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**Returnable/Refillable Bulk Containers-** Completely empty container. Do not rinse container. Return empty containers to point of purchase.

Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.



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ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL  
3721 E WIER AVE  
PHOENIX AZ 85040-2933  
602-438-0059 (PH)  
602-438-0407 (FAX)

Shanaz Bacchus, Regulatory Action Leader  
c/o Document Processing Desk  
Office of Pesticide Programs (7504P)  
Biopesticides & Pollution Prevention Division (BPPD)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501  
(703)308-8097

December 15, 2010

RE: Registration AF36 (Aspergillus flavus AF36) on Corn  
Company Number 71693-1 PP 9E7662

Dear Shanaz

Please find attached , a Notice of Filing and Form 8570-1 Application for Pesticide for the use of an atoxigenic *Aspergillus flavus* AF36 to displace toxigenic *Aspergillus flavus* on corn. This submission is in response to the letter from EPA dated October 6, 2010. This letter also authorizes EPA to review all pertinent data for *Aspergillus flavus* AF36 previously submitted to EPA in conjunction with this registration.

Sincerely,

Larry Antilla  
Sponsor and Submitter  
Staff Director  
Arizona Cotton Research and Protection Council



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
Amendment  
Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 71693	2. EPA Product Manager Shanaz Bacchus	3. Proposed Classification <input checked="" type="checkbox"/> Notto <input type="checkbox"/> Restricted
4. Company/Product [Name] Aspergillus flavus AF36	PM# 703-308-8097	
5. Name and Address of Applicant <i>[include ZIP Code]</i> Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933  <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____	

## Section - II

<input type="checkbox"/>	Amendment - Explain below.	<input type="checkbox"/>	Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/>	Resubmission in response to Agency letter dated <u>Oct 6, 2010</u>	<input type="checkbox"/>	"Me Too" Application.
<input type="checkbox"/>	Notification - Explain below.	<input type="checkbox"/>	Other - Explain below.


**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

This submission is in response to EPA's request for additional efficacy data on Corn as per the letter dated October 6, 2010.

## Section - III

1. Material This Product Will Be Packaged In:					2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) Bulk boxes, bags
* Certification must be submitted		If "Yes" Unit Packaging wgt. 1.8g		No. per container 1		
				If "Yes" Package wgt 1		No. per container 1
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container			4. Size(s) Retail Container Plastic bag, bulk box 50, 1000, 3000 lb		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point <i>(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</i>			
Name Michael Braverman, Ph.D		Title Biopesticide Manager, IR-4	Telephone No. (include Area Code) 732-932-9575ext 4610
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  (Stamped)
2. Signature 		3. Title Staff Director	
4. Typed Name Larry Antilla		5. Date 12-6-10	



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ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL  
3721 E WIER AVE  
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December 15, 2010

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Sincerely,

Larry Antilla  
Sponsor and Submitter  
Staff Director  
Arizona Cotton Research and Protection Council

# Aspergillus flavus AF36

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized)	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

### PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

**For other pesticide handlers under the scope of Worker Protection Standard:**

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

#### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

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#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

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#### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

##### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. **DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.**
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

#### STORAGE AND DISPOSAL

**DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.**

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**Returnable/Refillable Bulk Containers-** Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for feed use, or for drinking water, bathing, or other human/animal uses.

#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

# Aspergillus flavus AF36

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized)	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

## PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

**For other pesticide handlers under the scope of Worker Protection Standard:**

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

## ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated corn fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

##### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

#### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

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#### STORAGE AND DISPOSAL

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**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**Returnable/Refillable Bulk Containers-** Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.





RE: Aspergillus flavus AF 36 - EPA Reg. No. 71693-1 - PP 9E7662

Michael Braverman o Shanaz Bacchus

11/01/2010 02:07 PM

Cc: Iantilla, 'Peter Cotty', Sheryl Reilly

History: This message has been replied to.

Dear Shanaz

As per our conversation attached is a letter requesting a renegotiated PRIA date of August 18th, 2011.

I can appreciate that EPA has certain steps that need to be taken in the review of a package but there is very much a human component and great story of grower adoption of biopesticides connected with AF36. Part of your division is the Pollution Prevention Division and it is critical that we try to maintain growers interest in using biopesticides, especially when the grower and the registrant are so thoroughly integrated. To my knowledge this is the only true example of such grower adoption of biopesticides and the ability to maintain themselves as a viable organization may hinge on their ability to treat corn in the summer of 2011. I realize that you can't take any action until we resubmit, but we would appreciate whatever could be done to assist the Arizona Cotton Research and Protection Council by expediting the completion of the registration.

Sincerely

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Monday, November 01, 2010 12:24 PM

To: 'Michael Braverman'

Cc: Iantilla@azcotton.org; Peter Cotty

Subject: RE: Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP 9E7662

Thanks for your call this morning, Mike. In spite of your response being past the October 30, 2010, date that was included in the deficiency letter, I discussed the proposals with Sheryl and here are the options:  
1. IR-4 can request, on behalf of the registrant, to provide the efficacy data from 2009 and 2010 field trials with Aspergillus flavus AF36 on corn by January 18, 2011. This means that the data must be submitted to the Agency on or before that date, and must include analyses of cyclopiazonic acid (CPA), aflatoxin and other items as outlined in the deficiency letter dated October 6, 2010 (attached).

[See attached file: deficiency letter 71693-1 PP9E7662 10-06-10.pdf) 2.

Assuming that the data pass the 86-5 screen, they will be put into review and will require a processing time of 7 months. This includes processing and publishing a final rule to amend the tolerance exemption for *Aspergillus flavus* AF36, only if the data are acceptable and support such an amendment.

3. IR-4 needs to submit a request to negotiate the PRIA date from November 13, 2010, to August 18, 2011. If there are additional deficiencies further negotiation may be necessary.

4. If we do not receive a request to negotiate the PRIA date by COB today (11/01/10), the Agency will initiate the "cannot grant" letter for the proposed use of *Aspergillus flavus* AF36 on corn, because the data reviewed to date do not demonstrate that the pesticide is efficacious in this regard.

If you need to discuss this further, please call or email me.

Sincerely,

Shanaz Bacchus, Chemist

USEPA/OPP (Mail Code 7511P)

Biopesticides and Pollution Prevention Division 1200 Pennsylvania Ave., N.W.  
Washington D.C. 20460

Phone: 703-308-8097

Fax: 703-308-7026

Office Address:

2777 South Crystal Drive

One Potomac Yard, 8th Floor (S8945)

Crystal City, Arlington VA 22202

From: Shanaz Bacchus/DC/USEPA/US

To: "Peter Cotty" <pjcotty@email.arizona.edu>

Cc: "'Michael Braverman'" <braverman@AESOP.Rutgers.edu>, "'Larry Antilla'" <lantilla@azcotton.org>

Date: 10/27/2010 05:18 PM

Subject: RE: *Aspergillus flavus* AF36 - EPA Reg. No. 71693-1 - PP 9E7662

You just need to let him know when you can submit the report - give him a date. Then he will put in his processing time and I will add ours to propose a new due date. I need to have proposed dates that you think you can realistically keep (not packages) by tomorrow/Friday, so that I can

process the negotiation. Or else, we'll process "cannot grant" due to no response from registrant by deadline required for response.

Doe this help?

Sincerely,

Shanaz Bacchus, Chemist

USEPA/OPP (Mail Code 7511P)

Biopesticides and Pollution Prevention Division 1200 Pennsylvania Ave., N.W.

Washington D.C. 20460

Phone: 703-308-8097

Fax: 703-308-7026

From: "Peter Cotty" <pjcotty@email.arizona.edu>

To: Shanaz Bacchus/DC/USEPA/US@EPA

Cc: "'Michael Braverman'" <braverman@AESOP.Rutgers.edu>, "'Larry Antilla'" <lantilla@azcotton.org>

Date: 10/27/2010 03:45 PM

Subject: RE: Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP 9E7662

Shanaz,

Thanks. We have the data and it looks good. It is just time. I will discuss it with Michael and try to get him some drafts of the tables soon.

--Peter.

Peter J. Cotty

Agricultural Research Service, United States Department of Agriculture

School of Plant Sciences, University of Arizona

Desk: 520-626-5049

Secretary: 520-626-6775

FAX: 520-626-5944

Laboratory: 520-626-5704

Mail Address:

USDA-ARS

School of Plant Sciences

University of Arizona  
P.O. Box 210036  
Tucson, AZ 85721-0036

Address for Courier Delivery:  
Shantz Building, Room 115  
1177 E. Fourth Street  
Tucson, AZ 85721

Website: <http://cals.arizona.edu/research/cottylab/CottyLabHome.htm>

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [  
mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Wednesday, October 27, 2010 12:42 PM

To: Peter Cotty

Cc: 'Michael Braverman'; 'Larry Antilla'

Subject: RE: Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP 9E7662

Peter, do let Mike know when you can realistically prepare the report for submission and he can discuss time frames with us.

Thanks.

Sincerely,

Shanaz Bacchus, Chemist

USEPA/OPP (Mail Code 7511P)

Biopesticides and Pollution Prevention Division 1200 Pennsylvania Ave., N.W.  
Washington D.C. 20460

Phone: 703-308-8097

Fax: 703-308-7026

From: "Peter Cotty" <pjcotty@email.arizona.edu>

To: Shanaz Bacchus/DC/USEPA/US@EPA, "'Michael Braverman'"  
<braverman@AESOP.Rutgers.edu>

Cc: "'Larry Antilla'" <lantilla@azcotton.org>

Date: 10/27/2010 03:27 PM

Subject: RE: Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP  
9E7662

Michael,

This is my fault. I have been swamped and not had time to put together the report.

--Peter.

Peter J. Cotty  
Agricultural Research Service, United States Department of Agriculture  
School of Plant Sciences, University of Arizona  
Desk: 520-626-5049  
Secretary: 520-626-6775  
FAX: 520-626-5944  
Laboratory: 520-626-5704

Mail Address:  
USDA-ARS  
School of Plant Sciences  
University of Arizona  
P.O. Box 210036  
Tucson, AZ 85721-0036

Address for Courier Delivery:  
Shantz Building, Room 115  
1177 E. Fourth Street  
Tucson, AZ 85721

Website: <http://cals.arizona.edu/research/cottylab/CottyLabHome.htm>

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [  
mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Wednesday, October 27, 2010 12:24 PM  
To: Michael Braverman  
Cc: 'Larry Antilla'; 'Peter Cotty'  
Subject: Re: Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP 9E7662

Mike:

Please respond in writing for with a time line for providing the efficacy data from the field trials conducted with Aspergillus flavus AF36 on corn for the pending PRIA action. The PRIA deadline is November 13, 2010. If, alternatively, you wish to withdraw the registration action and pending amendment to the tolerance exemption, do notify us in writing. It takes two weeks to process a PRIA negotiation. If we do not hear from you, we may have to issue a "cannot grant" letter within that two week time frame..

I have placed two voice mails on your office phone and have sent a previous email to you regarding this matter. I am copying Larry Antilla and Peter Cotty so that they can understand the urgency of this matter.

Thanks for a prompt response.

Sincerely,

Shanaz Bacchus, Chemist  
USEPA/OPP (Mail Code 7511P)  
Biopesticides and Pollution Prevention Division 1200 Pennsylvania Ave., N.W.  
Washington D.C. 20460

Phone: 703-308-8097  
Fax: 703-308-7026

From: Shanaz Bacchus/DC/USEPA/US

To: Michael Braverman <braverman@AESOP.Rutgers.edu>

Date: 10/06/2010 11:57 AM

Subject: Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP 9E7662

(See attached file: deficiency letter 71693-1 PP9E7662 10-06-10.pdf)

Attached is the deficiency letter regarding Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP 9E7662. You have already received the review and phoned to tell me today that you have sent it to Dr. Peter Cotty. Generally, PRIA renegotiations are only approved when the data to satisfy the deficiencies are submitted to the Agency. However, since it may not be feasible for you to submit results from the 2009 and 2010 field trials (EPA Reg. No. 71693-EUP-2) by the PRIA due date (11/13/10), please submit in writing your commitment to provide the data by a certain time. Please include review time that BPPD would need in your request for a new PRIA date.

As discussed on the phone, I will be happy to discuss this matter further with you.

Sincerely,

Shanaz Bacchus, Chemist  
USEPA/OPP (Mail Code 7511P)  
Biopesticides and Pollution Prevention Division 1200 Pennsylvania Ave., N.W.  
Washington D.C. 20460  
Phone: 703-308-8097  
Fax: 703-308-7026

Office Address:  
2777 South Crystal Drive  
One Potomac Yard, 8th Floor (S8945)  
Crystal City, Arlington VA 22202



## EUP report AF 36 Pistachio

Michael Braverman o Shanaz Bacchus

09/22/2010 10:06 AM

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History: This message has been replied to.

---

Shanaz

Attached is the EUP report for AF36 Pistachio.

### The most significant conclusions

1. The proportion of the atoxigenic strain AF36 in the soil increased substantially in the treated orchards after applying the wheat-AF36 product, reaching up to 89% of the isolates three months after application.
2. Nuts from the orchards treated with the wheat-AF36 product were less likely to be contaminated with aflatoxin than those from nearby untreated orchards in 2008 and in 2009.
3. Application of the AF36 product did not increase the amount of cyclopiazonic acid (CPA) in the nuts.

I hope to convert this into a volume to support the section 3 registration soon.

Regards

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

*Need a biopesticide/organic pest control solution? Visit our label database.....*

<http://ir4.rutgers.edu/biopesticides.html>



EUP report late September 2010 [2].doc



af36PRIAextension.pdf





A  
C  
R  
P  
C

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL  
3721 E WIER AVE  
PHOENIX AZ 85040-2933  
602-438-0059 (PH) ex 1, 24  
602-438-0407 (FAX)

Dr. Michael McDavit, Acting Director  
Biopesticides & Pollution Prevention Division (BPPD)  
Office of Pesticide Programs (7511P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501  
(703)308-8097

November 8, 2010

RE: Registration representative for Arizona Cotton Research and Protection Council Company  
Number 71693

Dear Dr McDavit

As per my letter of August 8, 2002 to Dr Janet Andersen, the IR-4 Project represents the Arizona Cotton Research and Protection Council in any and all registration activities with EPA. On all 8570-1 Application for Pesticide forms, Dr Michael Braverman has been listed as the contact person regarding registrations and has continuously been our representative. This currently covers all actions involving *Aspergillus flavus* AF36. Therefore, we are requesting Dr Braverman be documented in your records as our representative in any and all regulatory activities. The following is his contact information:

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612  
[braverman@aesop.rutgers.edu](mailto:braverman@aesop.rutgers.edu)

Sincerely,

Larry Antilla  
Staff Director  
Arizona Cotton Research and Protection Council





## ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

3721 East Wier Avenue  
Phoenix, Arizona 85040-2933  
(602) 438-0059 - Phone  
(602) 438-0407 - Fax

August 8, 2002

Dr. Janet Andersen  
Biopesticide and Pollution Prevention Division  
c/o Document Processing Desk  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266 A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

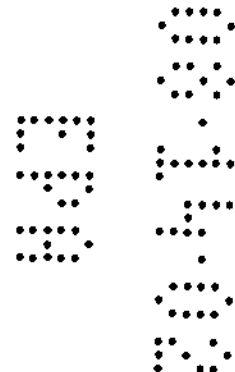
Subject: Aspergillus flavus AF-36 Arizona Cotton Research and Protection  
Council Company Number 71693

Dear Dr. Andersen:

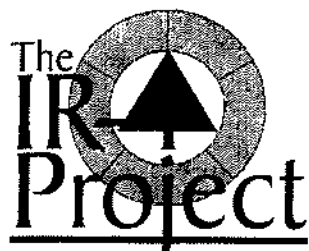
This letter authorizes the Environmental Protection Agency to refer to the Arizona Cotton Research and Protection Council data on Aspergillus flavus when considering the application for registration for Aspergillus flavus AF-36. This includes currently submitted data by USDA/ARS and the IR-4 Project in addition to data and waivers previously submitted for the Experimental Use Permit. We also authorize the IR-4 Project to act as our representative.

Sincerely,

Larry Antilla,  
Director







Providing Safe and Effective Pest  
Management Solutions for  
Specialty Crop Growers

IR-4 Headquarters  
Rutgers, The State University of New Jersey  
500 College Road East, Suite 201 W  
Princeton, NJ 08540  
732.932.9575  
fax: 609.514.2612  
[ir4.rutgers.edu](http://ir4.rutgers.edu)

Shanaz Bacchus, Regulatory Action Leader  
Document Processing Desk  
Office of Pesticide Programs (7504P)  
Biopesticides & Pollution Prevention Division (BPPD)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501  
(703)308-8097

November 1, 2010

Re: **Extension request:** Response to 75 day letter and PRIA renegotiation for  
Section 3 registration of *Aspergillus flavus* AF36 on corn. Company Number 71693.  
PP 9E7662

Dear Shanaz

I am writing this letter on behalf of the Arizona Cotton Research and Protection  
Council. The purpose of this letter is to request an extension on 2 related matters. 1)  
Extension for response to a 75 day letter, and 2) An extension/renegotiation of the  
PRIA timeline.

Thank you for the 75 day review letter dated October 6, 2010. We are in the process  
of organizing the information requested in the review and expect to submit our  
response by January 18, 2011. We will submit the efficacy and analyses of  
cyclopiazonic acid (CPA), aflatoxin and other items as outlined in the deficiency  
letter dated October 6, 2010 data from 2009 and 2010 field trials with *Aspergillus*  
*flavus* AF36 on corn by January 18, 2011. Since this would be beyond the deadline  
for a response to the 75 day letter, we are hereby requesting an extension for  
response to the 75 day letter until January 18<sup>th</sup>, 2011.

*Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES,  
in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.*

**RUTGERS**  
THE STATE UNIVERSITY  
OF NEW JERSEY

Since the current PRIA date is November 13, 2010 and we still need additional time to respond to the 75 day letter we are asking for a renegotiation of the PRIA date until August 18, 2011. We believe this will give us sufficient time to respond to the 75 day letter and account for the additional time that EPA needs to review the data. We sincerely hope that we can resubmit the additional data earlier and that EPA can subsequently complete the registration earlier as well. Please let me know if you concur with a new PRIA date of August 18, 2011.

Sincerely,

A handwritten signature in black ink, reading "Michael Braverman". The signature is fluid and cursive, with the first name "Michael" written in a larger, more prominent script than the last name "Braverman".

Michael Braverman  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612



RE: Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP 9E7662

Michael Braverman to: Shanaz Bacchus

11/01/2010 02:07 PM

Cc: lantilla, 'Peter Cotty', Sheryl Reilly

Dear Shanaz

As per our conversation attached is a letter requesting a renegotiated PRIA date of August 18th, 2011.

I can appreciate that EPA has certain steps that need to be taken in the review of a package but there is very much a human component and great story of grower adoption of biopesticides connected with AF36. Part of your division is the Pollution Prevention Division and it is critical that we try to maintain growers interest in using biopesticides, especially when the grower and the registrant are so thoroughly integrated. To my knowledge this is the only true example of such grower adoption of biopesticides and the ability to maintain themselves as a viable organization may hinge on their ability to treat corn in the summer of 2011. I realize that you can't take any action until we resubmit, but we would appreciate whatever could be done to assist the Arizona Cotton Research and Protection Council by expediting the completion of the registration.

Sincerely

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Monday, November 01, 2010 12:24 PM

To: 'Michael Braverman'

Cc: lantilla@azcotton.org; Peter Cotty

Subject: RE: Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP 9E7662

Thanks for your call this morning, Mike. In spite of your response being past the October 30, 2010, date that was included in the deficiency letter, I discussed the proposals with Sheryl and here are the options:

1. IR-4 can request, on behalf of the registrant, to provide the efficacy data from 2009 and 2010 field trials with Aspergillus flavus AF36 on corn by January 18, 2011. This means that the data must be submitted to the Agency on or before that date, and must include analyses of cyclopiazonic acid (CPA), aflatoxin and other items as outlined in the deficiency letter dated October 6, 2010 (attached).

(See attached file: deficiency letter 71693-1 PP9E7662 10-06-10.pdf) 2. Assuming that the data pass the 86-5 screen, they will be put into review and will require a processing time of 7 months. This includes processing and publishing a final rule to amend the tolerance exemption for Aspergillus flavus AF36, only if the data are acceptable and support such an amendment.

3. IR-4 needs to submit a request to negotiate the PRIA date from November 13, 2010, to August 18, 2011. If there are additional deficiencies further negotiation may be necessary.

4. If we do not receive a request to negotiate the PRIA date by COB today (11/01/10), the Agency will initiate the "cannot grant" letter for the proposed use of *Aspergillus flavus* AF36 on corn, because the data reviewed to date do not demonstrate that the pesticide is efficacious in this regard.

If you need to discuss this further, please call or email me.

Sincerely,  
Shanaz Bacchus, Chemist  
USEPA/OPP (Mail Code 7511P)  
Biopesticides and Pollution Prevention Division 1200 Pennsylvania Ave., N.W.  
Washington D.C. 20460  
Phone: 703-308-8097  
Fax: 703-308-7026

Office Address:  
2777 South Crystal Drive  
One Potomac Yard, 8th Floor (S8945)  
Crystal City, Arlington VA 22202

From: Shanaz Bacchus/DC/USEPA/US

To: "Peter Cotty" <pjccotty@email.arizona.edu>

Cc: "'Michael Braverman'" <braverman@AESOP.Rutgers.edu>, "'Larry Antilla'" <lantilla@azcotton.org>

Date: 10/27/2010 05:18 PM

Subject: RE: *Aspergillus flavus* AF36 - EPA Reg. No. 71693-1 - PP 9E7662

You just need to let him know when you can submit the report - give him a date. Then he will put in his processing time and I will add ours to propose a new due date. I need to have proposed dates that you think you can realistically keep (not packages) by tomorrow/Friday, so that I can process the negotiation. Or else, we'll process "cannot grant" due to no response from registrant by deadline required for response.

Does this help?



Sincerely,  
Shanaz Bacchus, Chemist  
USEPA/OPP (Mail Code 7511P)  
Biopesticides and Pollution Prevention Division 1200 Pennsylvania Ave., N.W.  
Washington D.C. 20460  
Phone: 703-308-8097  
Fax: 703-308-7026

From: "Peter Cotty" <pjcotty@email.arizona.edu>

To: Shanaz Bacchus/DC/USEPA/US@EPA

Cc: "'Michael Braverman'" <braverman@AESOP.Rutgers.edu>, "'Larry Antilla'" <lantilla@azcotton.org>

Date: 10/27/2010 03:45 PM

Subject: RE: Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP 9E7662

Shanaz,

Thanks. We have the data and it looks good. It is just time. I will discuss it with Michael and try to get him some drafts of the tables soon.

--Peter.

Peter J. Cotty  
Agricultural Research Service, United States Department of Agriculture  
School of Plant Sciences, University of Arizona  
Desk: 520-626-5049  
Secretary: 520-626-6775  
FAX: 520-626-5944  
Laboratory: 520-626-5704

Mail Address:  
USDA-ARS  
School of Plant Sciences  
University of Arizona  
P.O. Box 210036  
Tucson, AZ 85721-0036

Address for Courier Delivery:  
Shantz Building, Room 115  
1177 E. Fourth Street  
Tucson, AZ 85721

Website: <http://cals.arizona.edu/research/cottylab/CottyLabHome.htm>

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [  
mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Wednesday, October 27, 2010 12:42 PM  
To: Peter Cotty  
Cc: 'Michael Braverman'; 'Larry Antilla'  
Subject: RE: Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP 9E7662

Peter, do let Mike know when you can realistically prepare the report for submission and he can discuss time frames with us.

Thanks.

Sincerely,

Shanaz Bacchus, Chemist

USEPA/OPP (Mail Code 7511P)

Biopesticides and Pollution Prevention Division 1200 Pennsylvania Ave., N.W.

Washington D.C. 20460

Phone: 703-308-8097

Fax: 703-308-7026

From: "Peter Cotty" <pjcotty@email.arizona.edu>

To: Shanaz Bacchus/DC/USEPA/US@EPA, "'Michael Braverman'"  
<braverman@AESOP.Rutgers.edu>

Cc: "'Larry Antilla'" <lantilla@azcotton.org>

Date: 10/27/2010 03:27 PM

Subject: RE: Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP  
9E7662

Michael,

This is my fault. I have been swamped and not had time to put together the report.

--Peter.

Peter J. Cotty  
Agricultural Research Service, United States Department of Agriculture  
School of Plant Sciences, University of Arizona  
Desk: 520-626-5049  
Secretary: 520-626-6775  
FAX: 520-626-5944  
Laboratory: 520-626-5704

Mail Address:  
USDA-ARS  
School of Plant Sciences  
University of Arizona  
P.O. Box 210036  
Tucson, AZ 85721-0036

Address for Courier Delivery:  
Shantz Building, Room 115  
1177 E. Fourth Street  
Tucson, AZ 85721

Website: <http://cals.arizona.edu/research/cottylab/CottyLabHome.htm>

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [  
mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Wednesday, October 27, 2010 12:24 PM  
To: Michael Braverman  
Cc: 'Larry Antilla'; 'Peter Cotty'  
Subject: Re: Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP 9E7662

Mike:

Please respond in writing for with a time line for providing the efficacy data from the field trials conducted with Aspergillus flavus AF36 on corn for the pending PRIA action. The PRIA deadline is November 13, 2010. If, alternatively, you wish to withdraw the registration action and pending amendment to the tolerance exemption, do notify us in writing. It takes two weeks to process a PRIA negotiation. If we do not hear from you, we may have to issue a "cannot grant" letter within that two week time frame..

I have placed two voice mails on your office phone and have sent a previous email to you regarding this matter. I am copying Larry Antilla and Peter Cotty so that they can understand the urgency of this matter.

Thanks for a prompt response.

Sincerely,  
Shanaz Bacchus, Chemist  
USEPA/OPP (Mail Code 7511P)  
Biopesticides and Pollution Prevention Division 1200 Pennsylvania Ave., N.W.  
Washington D.C. 20460  
Phone: 703-308-8097  
Fax: 703-308-7026

From: Shanaz Bacchus/DC/USEPA/US

To: Michael Braverman <braverman@AESOP.Rutgers.edu>

Date: 10/06/2010 11:57 AM

Subject: Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP 9E7662

(See attached file: deficiency letter 71693-1 PP9E7662 10-06-10.pdf)

Attached is the deficiency letter regarding Aspergillus flavus AF36 - EPA Reg. No. 71693-1 - PP 9E7662. You have already received the review and phoned to tell me today that you have sent it to Dr. Peter Cotty. Generally, PRIA renegotiations are only approved when the data to satisfy the deficiencies are submitted to the Agency. However, since it may not be feasible for you to submit results from the 2009 and 2010 field trials (EPA Reg. No. 71693-EUP-2) by the PRIA due date (11/13/10), please submit in writing your commitment to provide the data by a certain time. Please include review time that BPPD would need in your request for a new PRIA date.

As discussed on the phone, I will be happy to discuss this matter further with you.

Sincerely,

Shanaz Bacchus, Chemist

USEPA/OPP (Mail Code 7511P)

Biopesticides and Pollution Prevention Division 1200 Pennsylvania Ave., N.W.  
Washington D.C. 20460

Phone: 703-308-8097

Fax: 703-308-7026

Office Address:

2777 South Crystal Drive

One Potomac Yard, 8th Floor (S8945)

Crystal City, Arlington VA 22202



FW: UPS Ship Notification , Tracking Number 1Z0061240299305852

Michael Braverman o Jeannine Kausch, Shanaz Bacchus

03/21/2011 07:41 PM

Jeannine and Shanaz

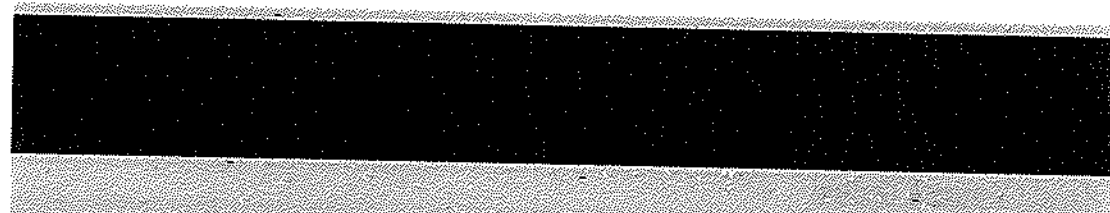
As a follow up to the electronic copy I sent earlier today, this is the UPS tracking number for the AF36 corn label amendment.

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

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<http://ir4.rutgers.edu/biopesticides.html>

**From:** UPS Quantum View [mailto:auto-notify@ups.com]  
**Sent:** Monday, March 21, 2011 2:59 PM  
**To:** braverman@AESOP.Rutgers.edu  
**Subject:** UPS Ship Notification, Tracking Number 1Z0061240299305852



This message was sent to you at the request of IR-4 Project Headquarters to notify you that the electronic shipment information below has been transmitted to UPS. The physical package(s) may or may not have actually been tendered to UPS for shipment. To verify the actual transit status of your shipment, click on the tracking link below or contact IR-4 Project Headquarters directly.

### **Important Delivery Information**

**Scheduled Delivery:** 23-March-2011

## Shipment Detail

### Ship To:

Jeannine Kausch  
USEPA BPPD  
Doc Proc Desk (7511P)  
One Potomac Yard  
2777 South Crystal Drive  
ARLINGTON  
VA  
222023553  
US

### Number of Packages:1

**UPS Service:** 2ND DAY AIR

**Weight:** 1.0 LBS

**Tracking Number:** 1Z0061240299305852

**Reference Number 1:** Sims Karen

**Reference Number 2:** AF36 Corn - ks

Click here to track if UPS has received your shipment or visit  
[http://www.ups.com/WebTracking/track?loc=en\\_US](http://www.ups.com/WebTracking/track?loc=en_US) on the Internet.

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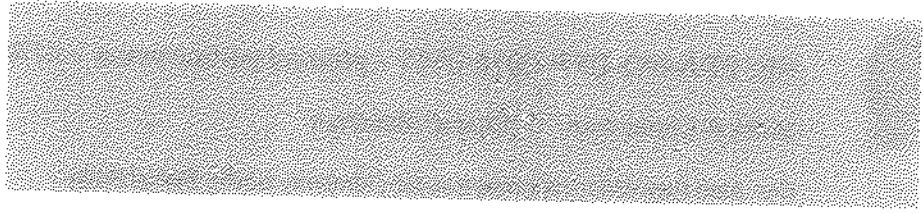
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RE: EPA-HQ-OPP-2010-0101 - product performance - AF36- corn

Michael Braverman o Shanaz Bacchus

03/21/2011 07:37 PM

Cc: Alan Reynolds, Jeannine Kausch, Kimberly Smith, Sheryl Reilly

Ok. Thanks

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

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-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Monday, March 21, 2011 4:28 PM

To: Michael Braverman

Cc: Reynolds.Alan@epamail.epa.gov; Kausch.Jeannine@epamail.epa.gov;

Smith.Kimberly@epamail.epa.gov; Reilly.Sheryl@epamail.epa.gov

Subject: RE: EPA-HQ-OPP-2010-0101 - product performance - AF36- corn

Thanks for the letter, Mike. To clarify, the first three pages of Dr. Gagliardi's review will be posted in the docket EPA-HQ-OPP-2010-0101 - not published in the Federal Register.

Sincerely,

Shanaz Bacchus

USEPA/OPP/BPPD/MPB

From: Michael Braverman <braverman@AESOP.Rutgers.edu>

To: Shanaz Bacchus/DC/USEPA/US@EPA, Kimberly

Smith/DC/USEPA/US@EPA

Cc: Sheryl Reilly/DC/USEPA/US@EPA, Alan

Reynolds/DC/USEPA/US@EPA, Jeannine Kausch/DC/USEPA/US@EPA

Date: 03/21/2011 02:41 PM

Subject: RE: EPA-HQ-OPP-2010-0101 - product performance - AF36- corn  
- resolved

Shanaz

Thanks for your e-mail and call. Hope my attached letter concerning no data confidentiality works for going forward with the FR publication.



Regards

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

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<http://ir4.rutgers.edu/biopesticides.html>

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Monday, March 21, 2011 2:23 PM  
To: Smith.Kimberly@epamail.epa.gov  
Cc: Reilly.Sheryl@epamail.epa.gov; Reynolds.Alan@epamail.epa.gov; Michael Braverman  
Subject: EPA-HQ-OPP-2010-0101 - product performance - AF36- corn - resolved

(See attached file: product performance AF36 corn OPP-2010-0101.pdf)  
Attached are three pages of the review re product performance of Aspergillus flavus AF36 on corn as discussed with you, Kimberly. This would not disclose personal privacy of the farmers who participated in the EUP and removes sections of the review labeled CBI.

Kimberly, please replace the original draft document with this one for the opening of the docket EPA-HQ-OPP-2010-0101.

Mike, this should make it easier for you to send us your CBI clearance letter.

Thanks,

Shanaz Bacchus

USEPA/OPP/BPPD/MPB

[attachment "AF36nodataconfidentialityMARCH212011.pdf" deleted by Shanaz Bacchus/DC/USEPA/US]



RE: EPA-HQ-OPP-2010-0101 - product performance - AF36- corn - resolved

Michael Braverman o Shanaz Bacchus, Kimberly Smith

03/21/2011 02:41 PM

Cc: Sheryl Reilly, Alan Reynolds, Jeannine Kausch

History: This message has been replied to.

Shanaz

Thanks for your e-mail and call. Hope my attached letter concerning no data confidentiality works for going forward with the FR publication.

Regards

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

Need a biopesticide/organic pest control solution? Visit our label database.....

<http://ir4.rutgers.edu/biopesticides.html>

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Monday, March 21, 2011 2:23 PM

To: Smith.Kimberly@epamail.epa.gov

Cc: Reilly.Sheryl@epamail.epa.gov; Reynolds.Alan@epamail.epa.gov; Michael Braverman

Subject: EPA-HQ-OPP-2010-0101 - product performance - AF36- corn - resolved

(See attached file: product performance AF36 corn OPP-2010-0101.pdf)  
Attached are three pages of the review re product performance of *Aspergillus flavus* AF36 on corn as discussed with you, Kimberly. This would not disclose personal privacy of the farmers who participated in the EUP and removes sections of the review labeled CBI.

Kimberly, please replace the original draft document with this one for the opening of the docket EPA-HQ-OPP-2010-0101.

Mike, this should make it easier for you to send us your CBI clearance letter.

Thanks,  
Shanaz Bacchus  
USEPA/OPP/BPPD/MPB



AF36nodataconfidentialityMARCH212011.pdf



**FW: Corn label amendment**

Michael Braverman o Jeannine Kausch

03/21/2011 01:55 PM

Cc: Shanaz Bacchus

Jeannine

Attached is a Word version of the revised AF36 label. As we discussed I have combined the 2 sublabels into 1 label with the state restrictions and application directions for cotton and corn.

I have also attached a complete PDF of the submission with the application form, cover letter EPA letter and stamped label and 5 copies of the new label.

Thanks for your assistance in processing this.

Sincerely

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612



AF36Cotton and Corn combined label.doc AF36cornamendlabelMarch2011.pdf



RE: FW: Your Submission to EPA (Reg. No. 71693-1, 1E7830)

Michael Braverman o Shanaz Bacchus

02/02/2011 08:14 PM

Cc: Fiker Getachew

Fiker and Shanaz

Attached are the data matrix and Certification with respect Data forms.

I noticed that the registrant dated the forms at the bottom of the page but did not insert the date toward the top. If this is essential, let me know and I will re-request.

Thanks

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

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<http://ir4.rutgers.edu/biopesticides.html>

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Tuesday, February 01, 2011 10:57 AM

To: Michael Braverman

Cc: Getachew.Fiker@epamail.epa.gov

Subject: Re: FW: Your Submission to EPA (Reg. No. 71693-1, 1E7830)

Mike:

Certification with Respect to Citation of Data and Data Matrix Forms are still missing. Please send those to Fiker and copy me.

Thanks,

Shanaz Bacchus

USEPA/OPP/BPPD (7511P)

flexphone: 301-570-0371

From: Michael Braverman <braverman@AESOP.Rutgers.edu>

To: Shanaz Bacchus/DC/USEPA/US@EPA

Date: 02/01/2011 10:02 AM

Subject: FW: Your Submission to EPA (Reg. No. 71693-1, 1E7830)

Shanaz

Is the request below from the EPA contractor the same as what we sent you.

Is it taken care of?

Thanks

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

Need a biopesticide/organic pest control solution? Visit our label database.....

<http://ir4.rutgers.edu/biopesticides.html>

-----Original Message-----

From: Getachew.Fiker@epamail.epa.gov [mailto:Getachew.Fiker@epamail.epa.gov]

Sent: Monday, January 31, 2011 2:16 PM

To: braverman@AESOP.Rutgers.edu

Subject: Your Submission to EPA (Reg. No. 71693-1, 1E7830)

Dear Mr. Braverman,

This is in-follow up to the voice message I left for you. We found the following deficiencies in your application package for *Aspergillus Flavus* AF36 (Reg. No. 71693-1 and Petition No. 1E7830). Certification with Respect to Citation of Data and Data Matrix Forms are missing from your application packages. The forms can be faxed to 703-305-5060: Attn: Fiker Getachew or emailed to me.

Thank You

Sincerely:

Fiker Getachew  
EPA Contractor  
703-305-6472



2011 02 02 AF36 Data Matrix and Cert.pdf



FW: Your Submission to EPA (Reg. No. 71693-1, 1E7830)

Michael Braverman o Shanaz Bacchus

02/01/2011 10:02 AM

---

History: This message has been replied to.

---

Shanaz

Is the request below from the EPA contractor the same as what we sent you.  
Is it taken care of?

Thanks

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

Need a biopesticide/organic pest control solution? Visit our label  
database.....

<http://ir4.rutgers.edu/biopesticides.html>

-----Original Message-----

From: Getachew.Fiker@epamail.epa.gov [mailto:Getachew.Fiker@epamail.epa.gov]

Sent: Monday, January 31, 2011 2:16 PM

To: braverman@AESOP.Rutgers.edu

Subject: Your Submission to EPA (Reg. No. 71693-1, 1E7830)

Dear Mr. Braverman,

This is in-follow up to the voice message I left for you. We found the following deficiencies in your application package for *Aspergillus Flavus* AF36 (Reg. No. 71693-1 and Petition No. 1E7830). Certification with Respect to Citation of Data and Data Matrix Forms are missing from your application packages. The forms can be faxed to 703-305-5060: Attn: Fiker Getachew or emailed to me.

Thank You

Sincerely:

Fiker Getachew  
EPA Contractor  
703-305-6472



**RE: AF36 Corn Label**

Michael Braverman o 'David Gibson', 'Scott Averhoff'

01/27/2011 01:50 PM

Cc: 'Larry Antilla', 'Peter J. Cotty', Shanaz Bacchus

History: This message has been forwarded.

Scott and David

I am not aware of any different type of application that could have been made to so called expedite or gain faster track review compared to what is already underway. I have discussed this with Shanaz and the review is underway in its normal course.

If you somehow become aware that there is something that can be done and it is within my power to assist, I would be glad to do so. I understand the urgency and appreciate your patience.

If you would like to discuss this further, please give me a call.

Shanaz- If there is any question that arises during the review process, please let me know as soon as possible.

Sincerely

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

Need a biopesticide/organic pest control solution? Visit our label database.....

<http://ir4.rutgers.edu/biopesticides.html>

-----Original Message-----

From: David Gibson [mailto:dgibson@texascorn.org]  
Sent: Wednesday, January 26, 2011 1:28 PM  
To: Bacchus.Shanaz@epamail.epa.gov  
Cc: Larry Antilla; Michael Braverman; Peter J. Cotty; Scott Averhoff  
Subject: Re: AF36 Corn Label

That didn't say much

David Gibson  
806-786-7265 cell  
800-647-2676 office

On Jan 26, 2011, at 12:23 PM, Bacchus.Shanaz@epamail.epa.gov wrote:

> The efficacy data submitted for Aspergillus flavus AF36 on corn are  
> currently under review.  
> Shanaz Bacchus

>  
>  
>  
>  
> From: "Larry Antilla" <lantilla@azcotton.org>  
> To: Shanaz Bacchus/DC/USEPA/US@EPA  
> Cc: "Michael Braverman" <braverman@AESOP.Rutgers.edu>, "Peter J.  
> Cotty" <pjcotty@email.arizona.edu>, "Scott Averhoff"  
> [REDACTED] "David Gibson"  
> <dgibson@texascorn.org>  
> Date: 01/26/2011 01:02 PM  
> Subject: AF36 Corn Label

>  
>  
> Shanaz,  
> I am trying to follow up on an inquiry by the corn producers led by  
> Scott Averhoff and David Gibson in Texas. They were asked by  
> congressional staff if we had requested an "expedited review" of the  
> label packet for corn. Being a novice at all this, I had no answer for  
> them. Perhaps you could shed some light on this matter. I know, based on  
> the truly excellent results that AF36 has produced in reducing aflatoxin  
> on their crops, that these growers are very concerned about losing  
> continuity on the progress that has been made to date. Thank you for your  
> consideration of this question.  
> Larry

>  
> Larry Antilla  
> Director  
> Arizona Cotton Research And Protection Council  
> 3721 E. Wier Ave  
> Phoenix AZ, 85040  
> (602)438-0059 Ext. 24  
>  
>





**RE: State Exemption**

Michael Braverman o Shanaz Bacchus

01/27/2011 09:11 AM

---

History: This message has been replied to.

---

Shanaz

I'm snowed in this morning. I'll try to call you when I get in.

Thanks

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

Need a biopesticide/organic pest control solution? Visit our label database.....

<http://ir4.rutgers.edu/biopesticides.html>

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Thursday, January 27, 2011 7:56 AM

To: Larry Antilla

Cc: Michael Braverman; Leovey.Elizabeth@epamail.epa.gov; Peter J. Cotty

Subject: Re: State Exemption

I do apologize for not clarifying that Mike can still be your consultant and that the link I sent you was for fee payment purposes only and is applicable if your group is part of the Arizona state government. That fee exemption status gives you more latitude regarding fee payments than making submissions as IR-4 actions. So while Mike can still submit on your behalf, the fee payments can be assessed under the state government fee exemption. I understand that it really allows you to make submissions such as amendments without having to include petitions as you would have to do if they are considered as IR-4 submissions. I will try to explain to Mike, since I haven't been able to discuss with you. Hope this helps.

Sincerely,

Shanaz Bacchus

USEPA/OPP/BPPD (7511P)

From: "Larry Antilla" <lantilla@azcotton.org>

To: Elizabeth Leovey/DC/USEPA/US@EPA, Shanaz  
Bacchus/DC/USEPA/US@EPA

Cc: "Peter J. Cotty" <pjcotty@email.arizona.edu>, "Michael

Braverman" <braverman@AESOP.Rutgers.edu>  
Date: 01/26/2011 05:46 PM  
Subject: State Exemption

Elizabeth,

I recently corresponded with Shanaz Bacchus to verify that the Arizona Cotton Research and Protection Council is an agency of the state of Arizona.. In her reply she offered the thought that it might be advantageous to submit applications (such as for use of our product AF36 on pistachios) as a state agency rather than through IR-4. I discussed the concept with my Council Chairman. Our conclusion was, while we very much appreciate Shanaz' thinking on our behalf, we have always relied on the considerable expertise of IR-4 to act on our behalf on these issues. In point of fact the Council has a very small staff and lacks the background and hands on experience to deal with complex regulatory matters. IR-4 as an entity, and Michael Braverman as an individual point of contact have been invaluable over the past several years in helping us work with EPA.. Being this close to the finish line we feel it is best to stay the course. Again thanks to both you and Shanaz for your interests on our behalf.

Larry Antilla

Director

Arizona Cotton Research And Protection Council

3721 E. Wier Ave

Phoenix AZ, 85040

(602)438-0059 Ext. 24



RE: Aspergillus flavus AF 36 - Pistachio

Michael Braverman o 'Tish Tamulis', Shanaz Bacchus

01/26/2011 01:50 PM

History: This message has been forwarded.

Shanaz

I assume the electronic versions that the Arizona Cotton Research and Protection Council sent are sufficient. If you need hard copies of anything that has been submitted by them or me, please let me know.

Thanks

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

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-----Original Message-----

From: Tish Tamulis [mailto:tish@azcotton.org]  
Sent: Wednesday, January 26, 2011 11:57 AM  
To: Bacchus.Shanaz@epamail.epa.gov  
Cc: Michael Braverman  
Subject: Aspergillus flavus AF36 - Pistachio

Requested documents signed and attached. Thanks so much.  
Tish Tamulis, Secretary to  
Larry Antilla  
Director, ACRPC

-----Original Message-----

From: Michael Braverman [mailto:braverman@AESOP.Rutgers.edu]  
Sent: Tuesday, January 25, 2011 12:43 PM  
To: Bacchus.Shanaz@epamail.epa.gov; Larry Antilla  
Cc: Downs.Teresa@epamail.epa.gov; Tish Tamulis  
Subject: RE: Aspergillus flavus AF36 - Pistachio

Shanaz

In regard to the issues regarding AF36 listed in your e-mail below, I have attached an amended cover letter and electronic Notice of Filing. If there is anything in what I have sent to you or Larry that needs changes, please let me know.

Larry

I have attached an updated 8570-1 Application form with an additional page. I have also attached an update Confidential Statement of Formula. Please sign and date these documents and return as an e-mail attachment to Shanaz. Please copy me as well

Thanks

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

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-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Monday, January 10, 2011 4:16 PM

To: Michael Braverman; lantilla@azcotton.org

Cc: Downs.Teresa@epamail.epa.gov

Subject: Aspergillus flavus AF36 - Pistachio

Mike:

Document processing informed me of your application on behalf of the Arizona Cotton and Research and Protection Council for the use of Aspergillus flavus AF36 on pistachio.

The following items are missing from the package.

1. The cover letter does not include the EPA Registration No. 71693-1 as the product to which the petition applies. The letter also does not request the exemption from tolerance. State both of these clearly in your cover letter.

2. Clearly state in your cover letter that the product is already registered and this is a proposed new use to add the crop pistachio to the label.

3. Thank you for so carefully separating out the health and ecological effects studies. However, we also need two copies of the following complete Data Matrices for EPA Registration No. 71693-1 as follows: one with a list of all the MRIDs that are to be considered for the action, and the second for the public. Specifically state in your cover letter whether the previously reviewed data support the new submission and why, and what new data are required for the new use. Also, explain why the new use will not pose an incremental risk to health and the environment greater than that which already exists for the current uses.

4. The 8570-1 form must include both the request for the exemption and the EPA Reg. No. for the product so that the Front Desk can process the package without having to try to figure out what pesticide product is to be used in

the applications.

5. The Confidential Statement of Formula form 8570-4 must include the EPA Registration No. in Box 4.

6. Explain what the articles included in each volume are supposed to support. Were they previously reviewed, and what are the new unreviewed articles that we need to consider in support of the petition.

7. Submit an electronic version of the petition that you would like us to publish in the docket when we announce the receipt of the petition.

Please submit all items by COB Friday, January 14, so that we can continue processing of this submission.

Sincerely,

Shanaz Bacchus, Chemist

USEPA/OPP (Mail Code 7511P)

Biopesticides and Pollution Prevention Division 1200 Pennsylvania Ave., N.W.  
Washington D.C. 20460

Phone: 703-308-8097

Fax: 703-308-7026

Office Address:

2777 South Crystal Drive

One Potomac Yard, 8th Floor (S8945)

Crystal City, Arlington VA 22202



**RE: Aspergillus flavus AF 36 - Pistachio**

Michael Braverman o Shanaz Bacchus, lantilla

01/25/2011 02:44 PM

Cc: Teresa Downs, 'Tish Tamulis'

---

History: This message has been forwarded.

---

Shanaz

In regard to the issues regarding AF36 listed in your e-mail below, I have attached an amended cover letter and electronic Notice of Filing. If there is anything in what I have sent to you or Larry that needs changes, please let me know.

Larry

I have attached an updated 8570-1 Application form with an additional page. I have also attached an update Confidential Statement of Formula. Please sign and date these documents and return as an e-mail attachment to Shanaz. Please copy me as well

Thanks

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

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-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Monday, January 10, 2011 4:16 PM

To: Michael Braverman; lantilla@azcotton.org

Cc: Downs.Teresa@epamail.epa.gov

Subject: Aspergillus flavus AF36 - Pistachio

Mike:

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2. Clearly state in your cover letter that the product is already registered and this is a proposed new use to add the crop pistachio to the label.

3. Thank you for so carefully separating out the health and ecological effects studies. However, we also need two copies of the following complete Data Matrices for EPA Registration No. 71693-1 as follows: one with a list of all the MRIDs that are to be considered for the action, and the second for the public. Specifically state in your cover letter whether the previously reviewed data support the new submission and why, and what new data are required for the new use. Also, explain why the new use will not pose an incremental risk to health and the environment greater than that which already exists for the current uses.

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7. Submit an electronic version of the petition that you would like us to publish in the docket when we announce the receipt of the petition.

Please submit all items by COB Friday, January 14, so that we can continue processing of this submission.

Sincerely,

Shanaz Bacchus, Chemist

USEPA/OPP (Mail Code 7511P)

Biopesticides and Pollution Prevention Division

1200 Pennsylvania Ave., N.W.

Washington D.C. 20460

Phone: 703-308-8097

Fax: 703-308-7026

Office Address:

2777 South Crystal Drive

One Potomac Yard, 8th Floor (S8945)

Crystal City, Arlington VA 22202



af36pistachioamendcoverletter1-26-2011.pdf af36pistachioforms1-26-2011.pdf AF36pistachio NOF2010.doc





**RE: Aspergillus flavus AF 36 - Pistachio**

Michael Braverman o Shanaz Bacchus, lantilla

01/18/2011 11:07 AM

Cc: Teresa Downs

History: This message has been replied to.

Shanaz

I have been out of the country and just got back in the office. I am scanning e-mails and recognize the importance of this one. I will get this to you in a couple of days.

Regards

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

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-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Monday, January 10, 2011 4:16 PM

To: Michael Braverman; lantilla@azcotton.org

Cc: Downs.Teresa@epamail.epa.gov

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Sincerely,

Shanaz Bacchus, Chemist

USEPA/OPP (Mail Code 7511P)

Biopesticides and Pollution Prevention Division

1200 Pennsylvania Ave., N.W.

Washington D.C. 20460

Phone: 703-308-8097

Fax: 703-308-7026

Office Address:

2777 South Crystal Drive

One Potomac Yard, 8th Floor (S8945)

Crystal City, Arlington VA 22202



FW: UPS Delivery Notification , Tracking Number 1Z0061240291313812

Michael Braverman o Shanaz Bacchus

12/16/2010 07:29 PM

Shanaz

According to the UPS the AF36 pistachio package has arrived.

Thanks

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

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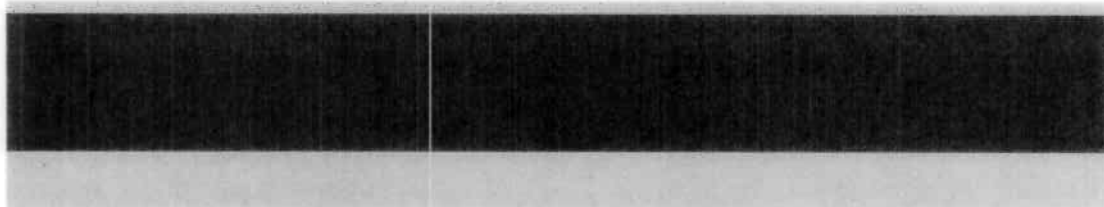
<http://ir4.rutgers.edu/biopesticides.html>

**From:** UPS Quantum View [mailto:auto-notify@ups.com]

**Sent:** Thursday, December 16, 2010 6:25 PM

**To:** braverman@AESOP.Rutgers.edu

**Subject:** UPS Delivery Notification, Tracking Number 1Z0061240291313812



\*\*\*Do not reply to this e-mail. UPS and IR-4 PROJECT RUTGERS UNIVERSITY will not receive your reply.

**At the request of IR-4 PROJECT RUTGERS UNIVERSITY, this notice is to confirm that the following shipment has been delivered.**

**Important Delivery Information**

**Tracking Number:** 1Z0061240291313812

**Delivery Date / Time:** 16-December-2010 / 3:33 PM

**Delivery Location:** MAIL ROOM  
**Signed by:** CARRIE

### **Shipment Detail**

**Ship To:**  
Shanaz Bacchus  
US EPA- BPPD  
2777 CRYSTAL DR  
ROOM 4900  
ARLINGTON  
VA  
22202  
US

**Number of Packages** 1  
**UPS Service:** 2ND DAY AIR  
**Weight:** 8.0 LBS  
**Reference Number 1:** Burke Ute  
**Reference Number 2:** Registration package

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RE: AF36 Pistachio

Michael Braverman o Shanaz Bacchus

12/14/2010 01:10 PM

Cc: 'John Inouye'

Shanaz

The AF36 application for Section 3 registration package and tolerance exemption petition for pistachio are together in one mailing.

In regard to AF36 corn, additional efficacy data will be sent out around the end of the week as a response to the 75 day letter. That is only to EPA

Regards

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

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-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Tuesday, December 14, 2010 12:19 PM

To: Michael Braverman

Cc: 'John Inouye'

Subject: Re: AF36 Pistachio

Thanks, Mike. Have we received a Section 3 application for pistachio?

I recall we have received one for corn.

Please clarify.

Shanaz Bacchus

USEPA/OPP/BPPD/MPB (7511P)

703-308-8097

From: Michael Braverman <braverman@AESOP.Rutgers.edu>

To: Shanaz Bacchus/DC/USEPA/US@EPA, 'John Inouye'  
<jinouye@cdpr.ca.gov>

Date: 12/14/2010 11:55 AM

Subject: AF36 Pistachio

Shanaz and John

Just a heads up that the AF36 Pistachio efficacy data is headed your way to support the Section 3 registration . I am submitting to both EPA and CDPR simultaneously, but realize that EPA approval is needed before CDPR can complete the California registration.

It should be at your respective document processing desks by Thursday.

Attached is an EPA notice of filing

Regards

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

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[attachment "AF36pistachio NOF2010.doc" deleted by Shanaz  
Bacchus/DC/USEPA/US]



AF36 Pistachio

Michael Braverman

t

o

:

Shanaz Bacchus, 'John Inouye'

12/14/2010 11:55 AM

History:

This message has been replied to.

Shanaz and John

Just a heads up that the AF36 Pistachio efficacy data is headed your way to support the Section 3 registration. I am submitting to both EPA and CDPR simultaneously, but realize that EPA approval is needed before CDPR can complete the California registration.

It should be at your respective document processing desks by Thursday.

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Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
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Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

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<http://ir4.rutgers.edu/biopesticides.html>



AF36pistachio NOF2010.doc



RE: letter of authorization - AF36

Michael Braverman o Shanaz Bacchus, Iantilla

11/12/2010 11:35 AM

Cc: Elizabeth Leovey, Michael Mcdavit, Sheryl Reilly, 'Jerry Baron', 'Tish Tamulis'

Shanaz

In addition to the scanned copy that I sent yesterday, I have received notification that the hard copy has been delivered to EPA today.

Please see tracking and signature information below. We look forward to your approval of the renegotiated PRIA date for *Aspergillus flavus* AF36 corn that was sent under separate cover.

Regards

This tracking update has been requested by:

Company Name: AZ COTTON RESEARCH COUNCIL

Name: Letitia Tamulis

E-mail: [tish@azcotton.org](mailto:tish@azcotton.org)

Message: Agent Letter

Our records indicate that the following shipment has been delivered:

Ship (P/U) date: Nov 10, 2010  
Delivery date: Nov 12, 2010 10:50 AM  
Sign for by: L. VISSE  
Delivery location: WASHINGTON, DC  
Delivered to: Receptionist/Front Desk  
Service type: FedEx Priority Overnight  
Packaging type: FedEx Envelope  
Number of pieces: 1  
Weight: 0.50 lb.  
Special handling/Services: Deliver Weekday

Tracking number: [796435861185](#)

Shipper Information

Letitia Tamulis  
AZ COTTON RESEARCH COUNCIL  
3721 E Wier Avenue  
Phoenix  
AZ  
US  
85040

Recipient Information

Dr. Michael McDavit, Acting Director  
Biopesticides & Pollution Prev BPPD  
One Potomac Yard 2777 S Crystal Dr  
USEPA Ofc Of Pesticide Pgms 7511P  
Arlington  
VA  
US  
22202

Please do not respond to this message. This email was sent from an unattended mailbox. This report was generated at approximately 9:56 AM CST on 11/12/2010.



To learn more about FedEx Express, please visit our website at [fedex.com](http://fedex.com).

All weights are estimated.

To track the latest status of your shipment, click on the tracking number above, or visit us at [fedex.com](http://fedex.com).

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Thank you for your business.

Michael Braverman, Ph.D.

Manager, Biopesticide and Organic Support Program

IR-4 Project, Rutgers University

500 College Road East, Suite 201W

Princeton, New Jersey 08540

Tel (732) 932-9575 ext 4610

Fax 609.514.2612

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<http://ir4.rutgers.edu/biopesticides.html>

**From:** Michael Braverman [mailto:[braverman@aesop.rutgers.edu](mailto:braverman@aesop.rutgers.edu)]

**Sent:** Thursday, November 11, 2010 8:34 AM

**To:** 'Bacchus.Shanaz@epamail.epa.gov'; 'lantilla@azcotton.org'

**Cc:** 'Leovey.Elizabeth@epamail.epa.gov'; 'Mcdavit.Michael@epamail.epa.gov';

'Reilly.Sheryl@epamail.epa.gov'; 'Jerry Baron'

**Subject:** RE: letter of authorization - AF36

Shanaz

I received a signed copy of the letter of authorization by FAX which I have scanned and attached.

A hard copy has been sent by the Arizona Cotton Research and Protection Council to Mike McDavit via FedEx. Please see tracking information below.

---

This tracking update has been requested by:

Company Name: AZ COTTON RESEARCH COUNCIL

Name: Letitia Tamulis

E-mail: [tish@azcotton.org](mailto:tish@azcotton.org)

Message: Agent Letter

---

Letitia Tamulis of AZ COTTON RESEARCH COUNCIL sent Dr. Michael McDavit, Acting Director

of Biopesticides & Pollution Prev BPPD 1 FedEx Priority Overnight package(s).

This shipment is scheduled to be sent on 11/10/2010.

Status: Shipment information sent to FedEx

Tracking number: 796435861185

Michael Braverman, Ph.D.

Manager, Biopesticide and Organic Support Program

IR-4 Project, Rutgers University

500 College Road East, Suite 201W

Princeton, New Jersey 08540

Tel (732) 932-9575 ext 4610

Fax 609.514.2612

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-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Tuesday, November 09, 2010 4:37 PM

To: lantilla@azcotton.org

Cc: Michael Braverman; Leovey.Elizabeth@epamail.epa.gov;

Mcdavit.Michael@epamail.epa.gov; Reilly.Sheryl@epamail.epa.gov

Subject: Re: Need letter of authorization - AF36

Larry, I just spoke with Mike and he has informed me that you have a letter naming him as agent for the Aspergillus flavus AF 36 actions. The authorization letter must also include Dr. Braverman's address and contact information. Please send that in on your letterhead ASAP. You may send a scanned signed copy in response to this email pending mailing of original signed copy. Our Potomac Yard 1 Office mailing address for FEDEX or overnight delivery is in the email below.

Thanks.

Shanaz Bacchus

301-570-0371 (flex phone).

From: Shanaz Bacchus/DC/USEPA/US

To: lantilla@azcotton.org

Cc: Michael Braverman <braverman@AESOP.Rutgers.edu>, Elizabeth Leovey/DC/USEPA/US@EPA

Date: 11/08/2010 04:12 PM

Subject: Need letter of authorization

In processing the negotiation of the PRIA date for the pending amendment of *Aspergillus flavus* AF36 on corn, it was brought to my attention that the attached letter on file for IR-4 to represent the Arizona Cotton Reasearch and Protection Council does not comply with the regulations as noted in

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=40:23.0.1.1.3&idno=40#40:23.0.1.1.3.3.1.6>

According to the CFR -

(3) Authorized agent. An applicant may designate a person residing in the United States to act as his agent. If an applicant wishes to designate an agent, he must send the Agency a letter stating the name and United States address of his agent. The applicant must notify the Agency if he changes his designated agent. This relationship may be terminated at any time by the applicant by notifying the Agency in writing.

[attachment "ir-4 rep az cotton 2002.pdf" deleted by Shanaz

Bacchus/DC/USEPA/US]

Larry, I am attaching the letter that we have used in the past for IR-4's representation of your actions. Please revise and state whether Dr. Braverman continues to represent you in all actions or only in all matters related to *Aspergillus flavus* AF 36. The representative must be a person and you must be specific on what actions he can represent. You may send me a scanned copy of the original that you put in the mail.

An urgent response is required to process the pending PRIA action (due date 11/13/10).

Sincerely,  
Shanaz Bacchus, Chemist  
USEPA/OPP (Mail Code 7511P)  
Biopesticides and Pollution Prevention Division  
1200 Pennsylvania Ave., N.W.  
Washington D.C. 20460  
Phone: 703-308-8097  
Fax: 703-308-7026

Office Address:  
2777 South Crystal Drive  
One Potomac Yard, 8th Floor (S8945)  
Crystal City, Arlington VA 22202

From: Shanaz Bacchus/DC/USEPA/US

To: [lantilla@azcotton.org](mailto:lantilla@azcotton.org)

Cc: Michael Braverman <[braverman@AESOP.Rutgers.edu](mailto:braverman@AESOP.Rutgers.edu)>, Elizabeth  
Leovey/DC/USEPA/US@EPA

Date: 11/08/2010 04:12 PM

Subject: Need letter of authorization

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<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=40:23.0.1.1.3&idno=40#40:23.0.1.1.3.3.1.6>

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[attachment "ir-4 rep az cotton 2002.pdf" deleted by Shanaz Bacchus/DC/USEPA/US]

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An urgent response is required to process the pending PRIA action (due date 11/13/10).

Sincerely,

Shanaz Bacchus, Chemist

USEPA/OPP (Mail Code 7511P)

Biopesticides and Pollution Prevention Division

1200 Pennsylvania Ave., N.W.  
Washington D.C. 20460  
Phone: 703-308-8097  
Fax: 703-308-7026

Office Address:  
2777 South Crystal Drive  
One Potomac Yard, 8th Floor (S8945)  
Crystal City, Arlington VA 22202



RE: letter of authorization - AF36

Michael Braverman o Shanaz Bacchus, Iantilla

11/11/2010 08:34 AM

Cc: Elizabeth Leovey, Michael McDavit, Sheryl Reilly, 'Jerry Baron'

---

Shanaz

I received a signed copy of the letter of authorization by FAX which I have scanned and attached.

A hard copy has been sent by the Arizona Cotton Research and Protection Council to Mike McDavit via FedEx. Please see tracking information below.

---

This tracking update has been requested by:

Company Name: AZ COTTON RESEARCH COUNCIL

Name: Letitia Tamulis

E-mail: [tish@azcotton.org](mailto:tish@azcotton.org)

Message: Agent Letter

---

Letitia Tamulis of AZ COTTON RESEARCH COUNCIL sent Dr. Michael McDavit, Acting Director of Biopesticides & Pollution Prev BPPD 1 FedEx Priority Overnight package(s).

This shipment is scheduled to be sent on 11/10/2010.

Status: Shipment information sent to FedEx

Tracking number: [796435861185](#)

Michael Braverman, Ph.D.

Manager, Biopesticide and Organic Support Program

IR-4 Project, Rutgers University

500 College Road East, Suite 201W

Princeton, New Jersey 08540

Tel (732) 932-9575 ext 4610

Fax 609.514.2612

Need a biopesticide/organic pest control solution? Visit our label database.....

<http://ir4.rutgers.edu/biopesticides.html>

-----Original Message-----

From: Bacchus.Shanaz@epamail.epa.gov [mailto:Bacchus.Shanaz@epamail.epa.gov]

Sent: Tuesday, November 09, 2010 4:37 PM

To: lantilla@azcotton.org

Cc: Michael Braverman; Leovey.Elizabeth@epamail.epa.gov;

Mcdavit.Michael@epamail.epa.gov; Reilly.Sheryl@epamail.epa.gov

Subject: Re: Need letter of authorization - AF36

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Thanks.

Shanaz Bacchus

301-570-0371 (flex phone).

From: Shanaz Bacchus/DC/USEPA/US

To: lantilla@azcotton.org

Cc: Michael Braverman <braverman@AESOP.Rutgers.edu>, Elizabeth  
Leovey/DC/USEPA/US@EPA

Date: 11/08/2010 04:12 PM

Subject: Need letter of authorization



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Washington D.C. 20460

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Office Address:

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From: Shanaz Bacchus/DC/USEPA/US

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AF36 Braverman.pdf



**RE: Need letter of authorization - AF36**

Michael Braverman o Shanaz Bacchus, Iantilla

11/10/2010 11:56 AM

Cc: Elizabeth Leovey, Michael Mcdavit, Sheryl Reilly

---

Shanaz

I spoke to Larry on the phone and he was in Mexico and is currently in Yuma. He will sign late this afternoon and I can get the LOA to you tomorrow morning.

Thanks

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
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**RE: Need letter of authorization**

Michael Braverman o 'Michael Braverman', Shanaz Bacchus,  
lantilla

11/08/2010 07:12 PM

Cc: Elizabeth Leovey, "Jerry Baron (Baron, Jerry)"

History: This message has been replied to and forwarded.

Shanaz

I have been having problems with accessing some files today. Hope the attachment comes through.

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
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<http://ir4.rutgers.edu/biopesticides.html>

-----Original Message-----

From: Michael Braverman [mailto:braverman@aesop.rutgers.edu]  
Sent: Monday, November 08, 2010 5:04 PM  
To: 'Bacchus.Shanaz@epamail.epa.gov'; 'lantilla@azcotton.org'  
Cc: 'Leovey.Elizabeth@epamail.epa.gov'; Jerry Baron (Baron, Jerry)  
Subject: RE: Need letter of authorization

Shanaz

The letter of Authorization you attached from 2002 does not pertain to corn, but does demonstrate a long term well established and well known relationship. Unfortunately others may not be aware of this relationship and of the knowledge and experience you possess.

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I have no doubt that Mr Antilla will re-confirm that I am an authorized representative.

If you need documentation regarding public interest, I can supply that as well.

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Manager, Biopesticide and Organic Support Program



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Cc: Michael Braverman; Leovey.Elizabeth@epamail.epa.gov

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loaf36corn.pdf



**RE: Need letter of authorization**

Michael Braverman o Shanaz Bacchus, Iantilla

11/08/2010 05:04 PM

Cc: Elizabeth Leovey, "Jerry Baron (Baron, Jerry)"

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Cc: Michael Braverman; Leovey.Elizabeth@epamail.epa.gov

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Explore Registrations

Reg Number: 71693-1

Reg. Type: Product Registration - Section 3

Status: Conditionally Registered (23-Jul-2010)

Name: Aspergillus Flavus AF36

<View Registration Details>

(No New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description
---	-----------------	----------------	--------------	-------------

...Decisions...

+ D: Closed; 424830; 71693-1;W03;IR-4 (100%);

+ D: Pending; 424829; 71693-1;B631;AMEND EST

Data Requirements

+ D: Closed; 368607; 71693-1;575;CONDITIONAL

+ D: Closed; 342307; 71693-1;300;LABEL REVISIO

+ D: Closed; 206011; 71693-1;157;DATA WAIVER

+ D: Pending; 206010; 71693-1;194;ACTION INITIA

+ D: Closed; 206009; 71693-1;194;ACTION INITIA

+ D: Closed; 206008; 71693-1;152;NEW INGREDI

+ D: Closed; 206007; 71693-1;010;NEW INGREDI

+ D: Closed; 206006; 71693-1;115;NEW INGREDI

Decision Sequence: 424829

Action: B631 AMEND ESTABLISHED TOLERANCE EXEMPTION;

Number: 71693-1 Original Decision:

Name: Aspergillus Flavus AF36

Decision Status: PENDING (18-Dec-2009)

Organization Owner: BPPD / MPB

Team Owner: RM 92

FFS Start Date: 13-Feb-2010 Received by Risk Manager:

Due Date: 13-Nov-2010 FFS Amt Expected: \$0

Negotiated Due Date: 17-Aug-2011 FFS Amt Refunded:

FFS Amt Received: \$0

Comments:

Explore Tolerance Petition

Petition Number: 9E7662

Company: ARIZONA COTTON RESEARCH AND PROTECT

Status: Under Review (15-Dec-2009)

Ingredients: 006456,Aspergillus flavus 36 colonized wheat seed,

<View Petition Details>

(No New Receipts)

S:	Submission Type	OPP Rec'd Date	Resubmission	Description
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...Decisions...

D: Pending; 424831; 9E7662;B631.0;AMEND ES

75-Day Letters

S: 864140 12/14/2009; New Registration; 7

S: 864140

Reg #: 9E7662

Submission Type: New Registration

Resubmission?: ☐ Yes ☒ No

Decision #: 424831; B631.0;AMEND ESTABLISHED TOLERANCE EXEMP1

Submitter Company: ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

Application Date: 01-Dec-2009

OPP Received Date: 14-Dec-2009

Date Sent to Risk manager: 15-Dec-2009

Studies Included?: ☐ Yes ☒ No

Fast Track?: ☐ Yes ☒ No

Form A Signed?: ☐ Yes ☐ No ☒ None

Date:

Form B Signed?: ☐ Yes ☐ No ☒ None

Date:

Reviewer: Bacchus, Shanaz

Received DT: 15-Dec-2009

Editable Due DT:


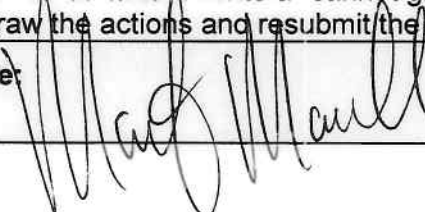
Submission Due DT: 17-Aug-2011

Response: 0 , 14-Dec-2009

Priority Weight:

Priority Points:

Comments:

Recommendation of Division Directors Negotiated Due Dates		
Decision #: 424829, 424831	Registration #: 71693-1	Petition #: 9E7662
Fee Category: B631, B631.0	PRIA Decision Time Frame: 9 months	
Submitted by: Shanaz Bacchus	Branch: MPB	Date: 11/02/2010
Company: Arizona Cotton Research and Protection Council		
Original Due Date: 11/13/2010	Proposed New Due Date: 08/17/2011	
Previous Negotiated Due Dates: NA		
Is the "Fix" in-house? No.	If not, date "Fix" expected: January 18, 2011	
<b>Issue (describe in detail):</b> <i>Aspergillus flavus</i> AF36 is registered under FIFRA Section 3(c) for treatment of cotton and is intended to displace the toxic, aflatoxin-producing pest, <i>A. flavus</i> , on treated commodities. Efficacy data are required for the public health hazard, aflatoxin, a potent liver carcinogen. The registrant has requested a Section 3 registration to add treatment of corn to the current label and filed a petition for a permanent exemption from tolerance for residues of <i>A. flavus</i> AF36 on corn. Submitted efficacy data and analyses of certain metabolites, including cyclopiazonic acid (CPA) from 2008 field trials of <i>A. flavus</i> AF36 on corn do not support these requests. The registrant intends to provide data from field trials conducted in 2009 and 2010 by January 18, 2011. The proposed new date is needed to allow BPPD time to review the submission and determine the acceptability of the application to amend the product and tolerance exemption for use of <i>Aspergillus flavus</i> AF36 on corn.		
<b>Summary of Deficiency Type(s):</b> Not Submitted (N) Deficiencies (D) <b>Product Chemistry:</b> <u>X</u> <b>Acute Tox:</b> <u>    </u> <b>Efficacy:</b> <u>X</u> <b>Labeling:</b> <u>    </u> <b>Other (describe):</b> D, N_ Efficacy data submitted from the 2008 field trial (EPA Reg. No. 71693-EUP-2) do not support the registration amendment request. Additional data from 2009 and 2010 field trials are required.		
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b> BPPD provided the company with its review of the efficacy data on September 23, 2010, and a 75 day letter was sent on October 06, 2010. Subsequent emails and phone calls were made to obtain a response to the deficiency letter by October 30, 2010. The company representative, IR-4, provided a letter on 11/01/10 stating that the data submissions will be made by January 18, 2011 and requested a negotiation of the PRIA date to 08/18/11.		
<b>"75 Day" Letter sent?</b> <u>Yes</u> (Date sent) 10/06/10 <u>    </u> No and reason for none?		
<b>Rationale for Proposed Due Date:</b> An additional seven months beyond the proposed submission date of January 18, 2011 is estimated as adequate (and appropriate for this code B631 action) for the Agency to review the efficacy data in order to determine acceptability and to respond to significant public comments dated 03/12/10 to the Notice of Receipt of the application published 02/10/10 (75FR 6656) as well as to prepare and publish a final rule if the data support the applications.		
<b>Registrant notified that this is the last negotiation?</b> <u>Yes</u> <u>x</u> Not Applicable		
Approve: 	Disapprove:	
<b>If disapproved, action to be taken:</b> Write a "cannot grant" letter prior to the 11/13/10 PRIA date or ask the registrant to withdraw the actions and resubmit the amendments when all the data are compiled.		
OD or DOD Signature: 	Date: 11-9-10	



## Checklist for Renegotiation Approval Process

Registration Package – D 424829, 424831

November 4, 2010

- (X) 2 copies of current form; Succinctly answer all questions, especially:
  - (1) is fix in? - NO
  - (2) if not, when will fix come in? January 18, 2011
  - (3) category of deficiency (i.e., efficacy)
- (X) 1 copy of e-mail or letter from Registrant/Consultant accepting new proposed date
- (X) Group decisions related to one action in one folder making sure that each decision number correlates with the registration action being renegotiated.

### Re-negotiation Approval Process

- (X) Place completed form in renegotiation box in Division Director's office
- ( ) Form to Doris Mack for log-in and routing to Marty Monell
- ( ) Form BPPD box then return form to BPPD Director or Renae Whitaker

### BPPD Processing Procedures

- ( ) Make date change in OPPIN and returned package to RAL
- ( ) Inform Mary Paden/Todd Peterson by email of due date change and cc: to appropriate Branch Chief
- ( ) Copy to Renae Whitaker
- ( ) Original to RAL
- ( ) RAL sends email with new date to applicant
- ( ) RAL electronically updates share/fees by scanning signed renegotiation form or saving file updated with approval date
- ( ) RAL either puts original form for single decision in relevant jacket or copies of signed form, if grouped, in each jacket, highlighting the decision number and jacket number that are correlated.
- ( ) RAL puts copies of all relevant emails in the relevant Jacket –

(F:\user\share\BPPD\Forms\Renegotiation Checklist)



**ROUTING AND TRANSMITTAL SLIP  
FOR PRIA RENEGOTIATION**

November 4, 2010

TO:

INITIALS/DATE

- |  |                      |
|--|----------------------|
| 1. Branch Chief:<br>Sheryl Reilly  | <u>SKR / 11-5-10</u> |
| 2. Michael McDavit, Acting Division Director<br>(place in Renegotiation box) | <u>WMA / 11-5-10</u> |
| 3. Doris Mack (Rm.S12624)  | <u>ADM / 11-5</u>    |
| 4. Marty Monell, Deputy Office Director                                      | <u>      /      </u> |
| 5. Doris Mack:<br>(copy to Elizabeth Leovey)                                 | <u>      /      </u> |
| 6. <del>Keith Matthews (Rm. S8723)</del><br>Renae Whitaker (Rm. S8321)       | <u>      /      </u> |

**Remarks:** Decisions 424829, 424831

*Aspergillus flavus* AF36 – establish tolerance exemption (PP9E7662)  
and Section 3(c) amendment to add corn to registered label 71693-1

Renegotiation from November 13, 2010 to August 18, 2011 for IR-4 to  
submit additional efficacy data by January 18, 2011 for Agency review.

FROM: Shanaz Bacchus Rm. #: S8945

PHONE #: 703-308-8097

(G:/user/share/BPPD/Forms/Routing Slip for Renegotiation)

*Rec  
ID*  
NOV 5 2010  
11300



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

February 16, 2010

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-424829  
EPA File Symbol or Registration Number: 71693-1  
Product Name: Aspergillus Flavus AF36  
EPA Application Receipt Date: 15-Dec-2009  
EPA Waiver Request Receipt date: 15-Dec-2009  
EPA Company Number: 71693  
Company Name: ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

CHARLENE R. NEAL  
ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL  
3721 EAST WIER AVENUE  
PHOENIX, AZ 85040-2933

SUBJECT: Fee Exemption

Dear Registrant:

The Office of Pesticide Programs has determined that the exemption in section 33(b)(7)(E) (exempting IR-4) of the Federal Insecticide, Fungicide, and Rodenticide Act applies to this action. Accordingly, there is no fee associated with the above referenced action. The decision review period for this action begins on the date of this letter.

The Action has been identified as Action code B631

AMEND ESTABLISHED TOLERANCE EXEMPTION;

If you have any questions, please contact Mr. Stephen Morrill, at (703) 308-8319.

Sincerely,

A handwritten signature in cursive script that reads "Kathryn Bonné for".

Oscar Morales, Director  
Information Technology & Resources Management Division  
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT 06 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, NJ 08540

Re: *Aspergillus flavus* AF36 - (EPA Reg. No. 71693-1)  
Proposed New Use on Corn - Data Deficiencies - MRID 47935101  
Product Performance Test Guidelines (OPPTS 810.1000)  
Amend Established Tolerance Exemption  
OPP Decision Numbers:  
D-424829 - EPA Reg. No. 71693-1  
D-424831 - Pesticide Petition: 9E7662 - *Aspergillus flavus* AF36  
Application Dated: November 11, 2009 and December 01, 2009, respectively.  
EPA Receipt Dates: December 15, 2009, for both applications

Dear Dr. Braverman:

The applications referred to above, submitted in connection with registration under FIFRA section 3(c)(5) have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD) and deficiencies have been identified in the *Aspergillus flavus* AF36 efficacy study on corn (MRID 47935101).

On September 23, 2010, BPPD met with you and provided a copy of its review (dated August 26, 2010) of the product performance (efficacy) data submitted for *Aspergillus flavus* AF36 on corn (MRID 47935101). Data are required from the studies conducted with *A. flavus* AF36 from an Experimental Use Permit (EUP; EPA Reg. No. 71693-EUP-2) in 2009 and 2010 from both Texas and Arizona to demonstrate the efficacy of *Aspergillus flavus* AF36 on corn. The report must include planting dates, AF36 treatment dates, stage of corn at treatment, conditions at and shortly after, treatment (i.e. irrigation or rain events), acres represented by each sample, number of samples per plot, type(s) of corn planted, distance(s) between plots, harvest dates, percent AF36 with aflatoxin and cyclopiazonic acid levels for each sample. Your response should include a discussion concerning whether areas located near the treated and untreated plots were treated with atoxigenic *Aspergillus flavus* AF36 or *Aspergillus flavus* NRRL 21882 (AflaGuard) previously for any testing and/or commercial purposes.

At the September 23, 2010 meeting, we also asked you consider whether an extension of the EUP might be needed, since it expires January 4, 2011; the associated temporary tolerance exemption for *Aspergillus flavus* AF36 on corn does not expire until December 30, 2011.

The referenced application as submitted under the Pesticide Registration improvement Act (PRIA) guaranteed a regulatory decision for the action category (B631) of 9 months. By regulation, the Agency is obligated to give you 75 days (40 CFR §152.105) in which to address the deficiencies identified above. However, there is not enough time remaining for you to submit the information and for BPPD to complete the review by the PRIA decision due date of November 13, 2010.

Therefore, you may renegotiate the PRIA due date or withdraw the application and resubmit it when you have all the information. Should you choose not to renegotiate the PRIA decision due date, or withdraw the application, the Agency will issue a letter stating that it cannot grant the application under PRIA on or about November 13, 2010. Please be advised that the resubmission of a withdrawn application will be considered a new application, and will be subject to a new registration decision time under PRIA. In the event the application is not granted, you will still have the remaining time (75 days from the date of this letter) in which to submit the required information. The Agency will continue to work on your application, but it will not be subject to the PRIA time frame. Please contact Shanaz Bacchus on or before October 30, 2010, by phone (703-308-8097) or by e-mail ([bacchus.shanaz@epa.gov](mailto:bacchus.shanaz@epa.gov)) with your response to this letter.

Sincerely,



Sheryl K. Reilly, Ph.D.  
Chief, Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

December 18, 2009

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-424829  
EPA File Symbol or Registration Number: 71693-1  
Product Name: Aspergillus Flavus AF36  
EPA Receipt Date: 15-Dec-2009  
EPA Company Number: 71693  
Company Name: ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

CHARLENE R. NEAL  
ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL  
3721 EAST WIER AVENUE  
PHOENIX, AZ 85040-2933

SUBJECT: Receipt of Amendment and IR-4 Fee Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application for amendment and IR-4 fee waiver request. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B631

AMEND ESTABLISHED TOLERANCE EXEMPTION;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If the determination indicates that payment is due, you will receive instructions for submitting payment at that time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-8260.

Sincerely,

  
Front End Processing Staff  
Information Technology & Resources Management Division

# Material to be added to a Mini-Jacket

(in the case where an e-Jacket exists)

EPA Reg. No. 71693-1

Send to Sig: check box ☒

This material is:

- ☒ New stamped- accepted label
- ☐ New CSF
- ☐ Notification
- ☐ Final Printed Label
- ☐ Registration Review Docs

Docket# EPA-HQ-OPP-

- ☐ Preliminary Work Plan
- ☐ Final Work Plan
- ☐ Final Decision
- ☐ FR Notices/Comments

☒ Other: Unconditional Registration – five batch submission  
evaluated and acceptable.

-----  
**Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this cover sheet to staff in the Information Services Center (Room 230)**

**Reviewer's Name:** Shanaz Bacchus **Phone:** 703-308-8097  
**Division:** BPPD **Date:** 11/28/07



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Biopesticides and Pollution Prevention Division (7511P)  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

EPA Reg.  
Number:

71693-1

Date of Issuance:

11-26-07

Term of  
Issuance:

Unconditional

Name of Pesticide Product:

*Aspergillus flavus* AF36

Name and Address of Registrant (include ZIP Code):

Arizona Cotton Research and Protection Council  
3721 East Wier Avenue  
Phoenix, Arizona 85040-2933

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

This product is registered in accordance with FIFRA Section 3(c)(5) provided that you do the following:

1. Submit/cite all data required for registration and registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
2. Submit production information for this product to the Agency in accordance with FIFRA Section 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year.

Signature of Approving Official:

*W. Michael McSat*

(See second page for signature)

Date:

11-26-07



3. This unconditional registration of *Aspergillus flavus* AF36 is for the use of the pesticide on cotton only in Arizona, California and Texas. A registration amendment is required to include *Aspergillus flavus* AF36 treatment of cotton in other states.
4. The Agency requires that, for use of *Aspergillus flavus* AF36 on other crops that are direct food commodities, you must submit efficacy data to demonstrate that the reduced aflatoxin-producing fungi post AF36 treatment correlate with reduction of aflatoxin levels. In addition, any proposed amendment of the registration must meet current Agency requirements and will be considered on a case-by-case basis.
5. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.

A stamped copy of the final draft label is enclosed for your records. If you have further questions, please email Shanaz Bacchus at [bacchus.shanaz@epa.gov](mailto:bacchus.shanaz@epa.gov) or call her on 703-308-8097.

Sincerely,

*W. Michael McDavit* 11/26/07

W. Michael McDavit, Associate Director  
Biopesticides and Pollution Prevention Division (7511P).



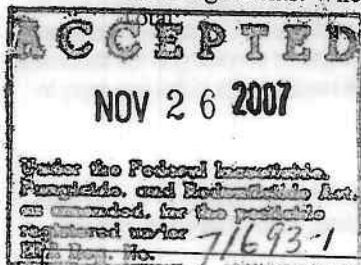
# Aspergillus flavus AF36

FOR USE ONLY IN THE STATES OF ARIZONA, TEXAS  
AND CALIFORNIA(Imperial, Riverside and San Bernadino counties only)

For displacing aflatoxin producing fungi

**Aspergillus flavus AF36** is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied to cotton just prior to first bloom, **Aspergillus flavus AF36** competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: *Aspergillus flavus* strain AF36\* ..... 0.0008%  
Other ingredients: Wheat seeds (sterilized, colonized)..... 99.9992%  
100%



\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

### First Aid Statement

IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693-1  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

## PRECAUTIONARY STATEMENTS

### HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

### For other pesticide handlers under the scope of Worker Protection Standard:

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

## ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other

waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated cotton fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

##### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

#### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to cotton to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed, which serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur at irrigation), *Aspergillus flavus* AF36 will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi are spread.

##### Ground Application:

1. Apply *Aspergillus flavus* AF36 with a cultivator mounted granular applicator to the surface of the soil under the plant canopy. **DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.**
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 under the canopy and to minimize delivery of *Aspergillus flavus* AF36 to furrows.
3. *Aspergillus flavus* AF36 has been shown to be effective when applied in late May or early June, prior to first bloom. Make a single application during the last cultivation before bloom.
4. Furrow irrigating the crop with at least 2 inches of water within three days after application of *Aspergillus flavus* AF36 will provide the best results.
5. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application may diminish efficacy.

#### STORAGE AND DISPOSAL

**DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.**

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

# The IR-4 Project

Providing Safe and Effective Pest  
Management Solutions for  
Specialty Crop Growers

IR-4 Headquarters  
Center for Specialty Crop Pest Management  
Rutgers, The State University of New Jersey  
681 US #1 South  
North Brunswick, NJ 08902-3390  
732.932.9575 fax: 732.932.8481  
www.ir4.rutgers.edu

Ms. Shanaz Bacchus  
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
c/o Front End Processing Desk (7504P)  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202  
(703)308-8097

Microbial biopesticide (AMEND)

June , 12, 2006

RE: AF36 Conditional Registration --Registration number 71693-1  
IR-4 PR# 52B

Dear Ms Bacchus:

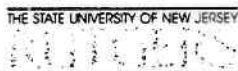
The purpose of this letter is to satisfy the conditional registration requirements for *Aspergillus flavus* AF36 (EPA Registration Number 71693-1) in cotton. The IR-4 Project is submitting this request on behalf of the Arizona Cotton Research and Protection Council. AF36 was conditionally approved on June 24, 2003(Attached). The 30 month period which was requested to submit the additional information was subsequently extended until June 24(see letter attached).

## Data volumes in this submission.

Volume 1 of 2 Microbial Product Analysis Data Requirements. *Aspergillus flavus* AF36

Volume 2 of 2 Microbial Product Performance Data. *Aspergillus flavus* AF36

*Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES,  
in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.*



Location of data in relation to items listed in the conditional registration data requirements.

Condition	Data Volume
5 batch analysis	1
Certification limits	1
Identification of <i>A. flavus</i> AF36 by either DNA analysis or some other method different from vegetative analysis	1
Analysis and quantification of metabolites and other unintentional ingredients, including aflatoxin	1
Identification and enumeration of potential human pathogens	1
Storage stability	1
Viability data	1
Efficacy data from large scale trials in Texas	2

Please let me know if you have any questions or anything else needs attention.

Sincerely,



Michael Braverman, Ph.D.  
Manager, Biopesticide Program  
IR-4 Project, Rutgers University  
681 U.S. Highway 1 South  
North Brunswick, New Jersey 08902-3390  
Phone 732-932-9575 ext 610  
FAX 732-932-8481

CC by e-mail: Peter Cotty, Larry Antilla

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 71693-1	2. EPA Product Manager Shanaz Bacchus	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Aspergillus flavus AF36	PM# (03) (703)308-8097	
5. Name and Address of Applicant (Include ZIP Code) Arizona Cotton Research and Protection Council 3721 E. Wier Avenue, Phoenix, Arizona 85040-2933  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This submission addresses additional data requirements that were part of the conditional registration dated June 24, 2003

## Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) _____
* Certification must be submitted If "Yes" Unit Packaging wgt. _____ No. per container _____		If "Yes" Package wgt. _____ No. per container _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container Plastic bag 50lb	5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Larry Antilla	Title Staff Director	Telephone No. (Include Area Code) 602-438-0059
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Staff Director	
4. Typed Name Larry Antilla	5. Date 6-7-06	



**VOLUME 3 OF SUBMISSION****STUDY TITLE**

Supplemental Information to  
Group A -- Product Analysis: *Aspergillus flavus* NRRL 21882:  
MRID No. 47008702

**DATA REQUIREMENT**

EPA OPTTS Guideline Reference Nos.  
885.1300  
885.1400

**AUTHOR**

Joe W. Dorner

**COMPLETION DATE**

July 26, 2007

**REPORT NO.**

980-01-56

**PREPARED BY**

United States Department of Agriculture  
National Peanut Research Laboratory  
1011 Forrester Drive, S.E.  
Dawson, GA 31742

**SPONSOR**

Circle One Global, Inc.  
One Arthur Street  
P.O. Box 28  
Shellman, GA 39886-0028



# DATA PACKAGE BEAN SHEET

Date: 28-Nov-2007

Page 1 of 2

Decision #: 368607

DP #: (330590)

NON PRIA

Parent DP#:

## \*\*\* Registration Information \*\*\*

Registration: 71693-1 - Aspergillus Flavus AF36

Company: 71693 - ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

Risk Manager: RM 92 - Dennis Szuhay - (703) 305-6098 Room# PY1 S-8761

Risk Manager Reviewer: Shanaz Bacchus SBACCHUS

Sent Date: 15-Jun-2006

Calculated Due Date: 02-Oct-2006

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (575) CONDITIONAL REGISTRATION FOLLOW-UP;DATA REQUIRED;REQUIRES SCIENCE

Ingredients: 006456, Aspergillus flavus 36 colonized wheat seed(.0008%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 05-Jul-2006

Due Back: \_\_\_\_\_

DP Ingredient: 006456, Aspergillus flavus 36 colonized wheat seed

DP Title: Cond reg submissions

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: \_\_\_\_\_

### Assigned To

#### Date In

#### Date Out

Organization: BPPD / MPB

05-Jul-2006

26-Nov-2007

Last Possible Science Due Date: 24-Jul-2006

Team Name: MPB Health & Characterization

05-Jul-2006

26-Nov-2007

Science Due Date: \_\_\_\_\_

Reviewer Name: Waggoner, Annabel

05-Jul-2006

26-Nov-2007

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Please review MRID 468595-01 and -02 to determine if the data support removing the conditions of registration for A. flavus AF36. The conditions for Product Characterization and 5 batch analyses and Product performance (Efficacy) under consideration are noted in the attached transmittal letter. If there are deficiencies in these submissions, state clearly what additional data are required to remove them. Do the data support unconditional registration of the pesticide? If you have any questions, do not hesitate to email me at bacchus.shanaz@epa.gov or call me on 703-308-8097.

Thanks



MRID	MRID Status	Citation Reference	Guideline
46859501	Acceptable	Cotty, P. (2006) Product Analysis, Limits, Identification, Determination of Unintentional Ingredients, Quality Control, Storage Stability and Viability: Aspergillus flavus AF36. Project Number: 0052B. Unpublished study prepared by U.S. Dept. of Agriculture, Agr.Res.Serv. and U.S. Dept. of Agriculture, Agric. Res. Serv. 112 p.	151-20/Product Identity and Disclosure of Ingredients
46859501	Acceptable	Cotty, P. (2006) Product Analysis, Limits, Identification, Determination of Unintentional Ingredients, Quality Control, Storage Stability and Viability: Aspergillus flavus AF36. Project Number: 0052B. Unpublished study prepared by U.S. Dept. of Agriculture, Agr.Res.Serv. and U.S. Dept. of Agriculture, Agric. Res. Serv. 112 p.	151-22/Discussion of Formation of Unintentional Ingredients
46859501	Acceptable	Cotty, P. (2006) Product Analysis, Limits, Identification, Determination of Unintentional Ingredients, Quality Control, Storage Stability and Viability: Aspergillus flavus AF36. Project Number: 0052B. Unpublished study prepared by U.S. Dept. of Agriculture, Agr.Res.Serv. and U.S. Dept. of Agriculture, Agric. Res. Serv. 112 p.	151-23/Analysis of Samples
46859501	Acceptable	Cotty, P. (2006) Product Analysis, Limits, Identification, Determination of Unintentional Ingredients, Quality Control, Storage Stability and Viability: Aspergillus flavus AF36. Project Number: 0052B. Unpublished study prepared by U.S. Dept. of Agriculture, Agr.Res.Serv. and U.S. Dept. of Agriculture, Agric. Res. Serv. 112 p.	151-25/Analytical Methods for Certified Limits
46859501	Acceptable	Cotty, P. (2006) Product Analysis, Limits, Identification, Determination of Unintentional Ingredients, Quality Control, Storage Stability and Viability: Aspergillus flavus AF36. Project Number: 0052B. Unpublished study prepared by U.S. Dept. of Agriculture, Agr.Res.Serv. and U.S. Dept. of Agriculture, Agric. Res. Serv. 112 p.	885.1300/Discussion of formation of unintentional ingredients
46859502	Acceptable	Cotty, P. (2006) Product Performance Data: Aspergillus flavus AF36. Project Number: 0052B. Unpublished study prepared by U.S. Dept. of Agriculture, Agr.Res.Serv. 38 p.	

# DATA PACKAGE BEAN SHEET

Date: 21-Nov-2007

Page 1 of 2

Decision #: 373073

DP #: (344181)

NON PRIA

Parent DP#:

## \*\*\* Registration Information \*\*\*

Registration: 75624-1 - ASPERGILLUS FLAVUS NRRL 21882

Company: 75624 - CIRCLE ONE GLOBAL, INC.

Risk Manager: RM 92 - Dennis Szuhay - (703) 305-6098 Room# PY1 S-8761

Risk Manager Reviewer: Joel Gagliardi JGAGLIAR

Sent Date: 27-Jul-2007

Calculated Due Date: 13-Nov-2007

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (575) CONDITIONAL REGISTRATION FOLLOW-UP;DATA REQUIRED;REQUIRES SCIENCE

Ingredients: 006500, Aspergillus flavus NRRL 21882(100%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 15-Aug-2007

Due Back: \_\_\_\_\_

DP Ingredient: 006500, Aspergillus flavus NRRL 21882

DP Title: Efficacy and product analyses - cond reg

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: \_\_\_\_\_

### Assigned To

### Date In

### Date Out

Organization: BPPD / MPB

15-Aug-2007

21-Nov-2007

Last Possible Science Due Date: 04-Sep-2007

Team Name: MPB Health & Characterization

15-Aug-2007

21-Nov-2007

Science Due Date: \_\_\_\_\_

Reviewer Name: Gagliardi, Joel

15-Aug-2007

04-Oct-2007

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Please review 470087-01, -02, 471892-01, -02 submitted to satisfy conditions of registration for Aspergillus flavus NRRL 21882. These studies are: 5 batch analyses and efficacy data. Summarize deficiencies, if any, and state clearly what data are required to satisfy those deficiencies. If you have any questions, please email, call or stop by.  
Thanks

MRID	MRID Status	Citation Reference	Guideline
47008701	Acceptable	Dorner, J. (2006) Efficacy Study: Field Trial with Afla-guard. Project Number: 980/01/52. Unpublished study prepared by U.S. Dept. of Agriculture. 54 p.	810.1000/Overview, Definitions, and General Considerations
47008702	Supplemental	Gaughan, R. (2006) Group A -- Product Analysis: Aspergillus Flavus NRRL 21882. Project Number: 980/01/53. Unpublished study prepared by Acta Group, L.L.C. 29 p.	885.1300/Discussion of formation of unintentional ingredients
47008702	Supplemental	Gaughan, R. (2006) Group A -- Product Analysis: Aspergillus Flavus NRRL 21882. Project Number: 980/01/53. Unpublished study prepared by Acta Group, L.L.C. 29 p.	885.1400/Analysis of samples
47008702	Supplemental	Gaughan, R. (2006) Group A -- Product Analysis: Aspergillus Flavus NRRL 21882. Project Number: 980/01/53. Unpublished study prepared by Acta Group, L.L.C. 29 p.	885.1500/Certification of limits
47189201	Acceptable	Dorner, J. (2007) Supplemental Information to Efficacy Study: Field Trial with Afla-guard. Project Number: 980/01/55, 0/001/6/00006911/DOC. Unpublished study prepared by U.S. Dept. of Agriculture. 32 p.	810.1000/Overview, Definitions, and General Considerations
47189202	Supplemental	Dorner, J. (2007) Supplemental Information to Group A: Product Analysis: Aspergillus flavus NRRL 21882. Project Number: 980/01/56. Unpublished study prepared by Circle One Global Inc. 30 p.	885.1300/Discussion of formation of unintentional ingredients
47189202	Supplemental	Dorner, J. (2007) Supplemental Information to Group A: Product Analysis: Aspergillus flavus NRRL 21882. Project Number: 980/01/56. Unpublished study prepared by Circle One Global Inc. 30 p.	885.1400/Analysis of samples

# DATA PACKAGE BEAN SHEET

Date: 21-Nov-2007

Page 1 of 2

Decision #: 382175

DP #: (344183)

NON PRIA

Parent DP#:

## \*\*\* Registration Information \*\*\*

Registration: **75624-2 - AFLA-GUARD**

Company: 75624 - CIRCLE ONE GLOBAL, INC.

Risk Manager: RM 92 - Dennis Szuhay - (703) 305-6098 Room# PY1 S-8761

Risk Manager Reviewer: Joel Gagliardi JGAGLIAR

Sent Date: 27-Jul-2007

Calculated Due Date: 13-Nov-2007

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (575) CONDITIONAL REGISTRATION FOLLOW-UP;DATA REQUIRED;REQUIRES SCIENCE

Ingredients: 006500, Aspergillus flavus NRRL 21882(.01%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 15-Aug-2007

Due Back: \_\_\_\_\_

DP Ingredient: 006500, Aspergillus flavus NRRL 21882

DP Title: Efficacy & Pchem 5 batch

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: \_\_\_\_\_

### Assigned To

#### Date In

#### Date Out

Organization: BPPD / MPB

21-Nov-2007

Last Possible Science Due Date: 04-Sep-2007

Team Name: MPB Health & Characterization

21-Nov-2007

Science Due Date: \_\_\_\_\_

Reviewer Name: Gagliardi, Joel

04-Oct-2007

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Please refer to D 373073 and DP 344181 for instructions to review efficacy and 5 batch analyses for conditions of registration for 75624-EUP-1 and -2.  
Thanks,  
shawn



**Shanaz  
Bacchus/DC/USEPA/US**

02/13/2007 04:53 PM

To John Kough/DC/USEPA/US@EPA, Annabel  
Waggoner/DC/USEPA/US@EPA

cc

bcc

Subject FW: FW:Cotton unconditional registration and plans for food  
crop quality control -- AF36

Below is Mike Braverman's response to questions raised regarding review of data for the unconditional registration of *Aspergillus flavus* AF36. Please let me know if these responses address the queries or if we need to have a teleconference to clarify any issues.

shawn

Phone: 703-308-8097

----- Forwarded by Shanaz Bacchus/DC/USEPA/US on 02/13/2007 04:49 PM -----



**Michael Braverman**  
**<braverman@AESOP.Rutgers.edu>**

02/13/2007 03:26 PM

To Shanaz Bacchus/DC/USEPA/US@EPA

cc

Peter Cotty <pjcotty@email.arizona.edu>, Larry Antilla  
<LAntilla@Azcotton.org>

Subject FW: FW: FW:Cotton unconditional registration and plans for  
food crop quality control

Shanaz

This is in response to your e-mail of questions back on January 16. I have pieced together responses from Peter, the laboratory that conducted the aflatoxin analysis and sections of previous submissions. Hope I pasted everything in the right spot.

Your original questions should appear in black and responses are in blue. There are 4 attachments.

Michael Braverman, Ph.D.  
Manager, Biopesticide Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612

---

**From:** Peter J. Cotty [mailto:pjcotty@email.arizona.edu]

**Sent:** Tuesday, January 30, 2007 3:49 PM

**To:** Michael Braverman

**Cc:** Larry Antilla

**Subject:** RE: FW: FW:Cotton unconditional registration and plans for food crop quality control

Michael,

1. The certified limits are out of recommended range - clarify and explain why these are the ranges that you need if special circumstances apply.

All batches far exceed the minimum requirements for *A. flavus* growth and spore yield (minimum requirement of yielding  $2.5 \times 10^9$  spores per gram). However, there is considerable variability among batches in spore yield. This is a good assay directly related to how the product is designed to perform in the field. However, it is not a chemical assay, it is an assay of growth and reproduction of an organism on a natural, but variable substrate (wheat). The variability among batches is the sum of several variabilities. These include variation among days on which the assay was run. Although, the assay is performed under standard conditions, it is a biological assay and there can be assumed to be variability among dates of assay independent of variability in the product. In the assay, the fungus is actually growing on the wheat-seed carrier (actually a food substrate for the fungus). Batches of wheat seed also vary and the spore yield partially reflects this. Also, the fungus spores produced on different days also have some variation. The variability between batches existed throughout the lengthy experimental use program and no detrimental impact was detected. Because of the biological nature of the product, the variability in spore yield should be acceptable, so long as the yield exceeds the minimum required.

The formulation is steam sterilized wheat seed colonized by a strain of *Aspergillus flavus*. The form of the fungus on the seed is for the most part mycelium (i.e. hyphal strands adhering to the seed coat). The quality parameter of greatest relevance to field performance is the ability of the colonized wheat to support growth and sporulation of strain AF36. Therefore, the parameter that is monitored on every batch is spore yield by the product under standardized conditions for a standard period of time following the procedures detailed in the quality control protocols previously submitted. The 3,000 CFU/g is obtained by taking the end use product and grinding it in a laboratory mill in order to break up the seed. The number of propagules detected is dependent upon how times the mycelium coating the seed is broken during the process (each mycelial fragment is detected as one propagule). We do not routinely assay this because it is artificial, highly dependent on the exact grinding technique, and not clearly relevant to product performance in the field. The 3,000 CFU/g quantity was developed at the request of EPA specifically for the label.

2. The identification of the samples is missing.
2. All samples appear to be numbered with an identification code. It is not clear which section you believe has unidentified samples.
3. The methods for detection of human pathogens are missing - also please look at the BRAD online pp. 45 and 46 of the BRAD, where we asked for identification and enumeration of human pathogens. The previous

studies (a) MRID 43763402 reviewed by Cindy Schaeffer needed more information on human pathogens and metabolites; MRID 446261-01 reviewed by Dr. Michael Watson relied on a count of coliforms and bacteria, and did not identify and enumerate the contaminants).

3. Please look at attachment ( PDF of MRID 44626101). On page 10 of 28 it mentions the quality control procedures using Violet Red Bile Agar for identification of coliforms and the specifications for the end use product. In the DER of attachment MRID 44626101, Mike Watson clearly cited the quality control method and the specifications for the end use product on page 4 of the DER. On page 4 of the DER Mike stated that the submission was acceptable except for aflatoxin production and identification of *A. flavus*. In addition, these exceptions were listed under the conclusions on page 1 of the DER, The limits stated were < 6 of 50 of bacteria(12%) and <2 of 50 seeds(2%) with coliform.

In the 5 batch analysis 4 out of the 5 batches had 0 bacteria and 0 *Enterobacteria*(Coliform). These low levels of contamination are due to the fact that the wheat is sterilized before inoculation with AF36

Only one batch had 1% bacteria and 0% coliform, therefore these are well below the acceptable limits as accepted by Mike Watson. More specifically, this is being applied to soil which is replete with coliform and other bacteria and the number is below the acceptable limit, therefore identification is not warranted. As in all cases there is also a 0 tolerance for any *A. flavus* , that is not AF36.

Therefore both the quality control method and the results of the 5 batch analysis are acceptable.

4. There is no positive control or standard curve to show that the HPLC method is capable of detecting and quantifying aflatoxin levels.

4. A copy of the method from Romer Labs is attached. For the spike, total concentration was 5 ug/mL or 40 ppb when calculated through the method. For B1 and G1 it is equal to 2.0 ug/mL each or 16 ppb each calculated out. For B2 and G2 it is equal to 0.5 ug/mL each or 4 ppb each calculated out. Total concentration was 5 ug/mL or 40 ppb when calculated through the method. For B1 and G1 it is equal to 2.0 ug/mL each or 16 ppb each calculated out. For B2 and G2 it is equal to 0.5 ug/mL each or 4 ppb each calculated out. Total concentration was 5 ug/mL or 40 ppb when calculated through the method. For B1 and G1 it is equal to 2.0 ug/mL each or 16 ppb each calculated out. For B2 and G2 it is equal to 0.5 ug/mL each or 4 ppb each calculated out.

The percent recovery for the spikes were:

B1: 98.0%  
B2: 94.3%  
G1: 109.1%  
G2: 104.4%



The 1 ppb LOD was determined through an internal validation data. This LOD was determined both by standard injections themselves and by extrapolated data based on signal-to-noise ratios for the method.

A standard curve was not used to calibrate the equipment. A single level standard was used. The standard was injected a minimum of three separate times. The first three individual standard injections were used for calibration. The calibration is performed on 3 individual standards but at one concentration level. The standard injections used are injection #1, #7, and #13 of the batch run. Our samples were #17-#26 of the batch run with a non-calibration standard injection made #21; between samples 3 (C-341) and 4 (D-451).



If any of these were part of a previously reviewed submission, please let me know what MRID we should look at or send a scanned DER to support your submission and clarify the issues. Some of the previous submissions you referred to in this new submission are: 43763401, 43763402, 44597001, 44626101.

B. Regarding the need for aflatoxin levels on edible food commodities. From a preliminary discussion with John Kough, we are looking for reduced aflatoxin levels in/on edible food commodities rather than reduced colonies of aflatoxin-production fungi. Even though the levels of aflatoxin on the nuts may not be the FDA levels, we still have to start measuring aflatoxin levels rather than colonies of toxigenic *A. flavus*. So from a regulatory point of view, the labels will be different for the edible commodities and not be the same as for cotton.

B. I understand the difference for food crops such as pistachio. Data on aflatoxin levels in treated and non-treated pistachio will be developed through the course of the EUP.

Looking, I also wanted to re-examine Question #3 in regard to food crops. For application to soil in the cotton crop, the limits stated were < 6 of 50 of bacteria(12%) and <2 of 50 seeds(2%) with coliform. For food crops we propose to have the quality control limits of 0 of 50 seeds contaminated with bacteria and 0 of 50 seeds contaminated with coliform. Therefore any batch contaminated with bacteria or coliform will be discarded.

We believe that for cotton, the established tolerances are acceptable but want to be proactive in regard to food crops. If this is acceptable, please let me know and I will submit an amendment to MRID 44626101 so that for food crops, the 0 tolerance levels will be documented for food crops and this will take care of this issue for pistachio.



Afla kobra hplc 00.1.doc Five Batch Analysis.doc AF36sampleanalysisMRID44626101.pdf AF36DERofMRID44626101.pdf

